

**FEDERAL REGISTER**

VOLUME 4

NUMBER 89

*Washington, Tuesday, May 9, 1939*

**The President**

NATIONAL MARITIME DAY—1939  
BY THE PRESIDENT OF THE UNITED STATES  
OF AMERICA

A PROCLAMATION

WHEREAS on May 22, 1819, the steamship *The Savannah* sailed from Savannah, Georgia, on the first successful transoceanic voyage under steam propulsion, thus making a material contribution to the advancement of ocean transportation; and

WHEREAS the Congress by joint resolution approved May 20, 1933 (48 Stat. 73), designated May 22 of each year as National Maritime Day and requested the President to issue annually a proclamation calling upon the people of the United States to observe such National Maritime Day; and

WHEREAS it is fitting that the enterprise and achievements of the American merchant marine and the courage and patriotism of the officers and seamen of that merchant marine throughout our history be thus recognized;

NOW, THEREFORE, I, FRANKLIN D. ROOSEVELT, President of the United States of America, do hereby call upon the people of the United States to observe May 22, 1939, as National Maritime Day by displaying the flag at their homes or other suitable places and do direct Government officials to display the flag on all Government buildings on that day.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the seal of the United States of America to be affixed.

DONE at the City of Washington this 4<sup>th</sup> day of May in the year [SEAL] of our Lord nineteen hundred and thirty-nine, and of the Independence of the United States of

America the one hundred and sixty-third.

FRANKLIN D. ROOSEVELT

By the President:

CORDELL HULL  
*Secretary of State.*

[No. 2334]

[F. R. Doc. 39-1548; Filed, May 6, 1939;  
1:00 p. m.]

NATIONAL FLOOD PREVENTION WEEK  
BY THE PRESIDENT OF THE UNITED STATES  
OF AMERICA

A PROCLAMATION

WHEREAS Public Resolution No. 129, 75th Congress, approved June 29, 1938 (52 Stat. 1248), provides:

That the Honorable Franklin D. Roosevelt, President of the United States, be, and he is hereby requested to proclaim the week of May 31, 1939, National Flood Prevention Week in the United States of America, and to ask the cooperation, interest, and aid of all the people in the work of flood prevention;

NOW, THEREFORE, I, FRANKLIN D. ROOSEVELT, President of the United States of America, do hereby proclaim the week beginning May 31, 1939, as National Flood Prevention Week, and do call upon the people of the United States to cooperate and aid in the work of flood prevention and to give serious consideration to such measures as may prevent disastrous floods and aid in the conservation of our national resources.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the seal of the United States of America to be affixed.

DONE at the City of Washington this 4<sup>th</sup> day of May, in the year [SEAL] of our Lord nineteen hundred and thirty-nine, and of the

**CONTENTS**

**THE PRESIDENT**

Proclamations:	Page
National Flood Prevention Week	1921
National Maritime Day, 1939	1921

**RULES, REGULATIONS,  
ORDERS**

TITLE 6—AGRICULTURAL CREDIT: Farm Security Administration: Greenbelt, Greendale and Greenhill Projects, rights, etc., under leases of com- mercial enterprises	1947
---	------

TITLE 7—AGRICULTURE: Agricultural Adjustment Admin- istration: Cotton pool participation trust certificates, Form C-5-I, retirement of; amend- ments	1947
--	------

Federal Crop Insurance Corpo- ration: Wheat crop insurance, regu- lations amended	1947
--	------

TITLE 8—ALIENS AND CITIZENSHIP: Immigration and Naturalization Service: Gateway, Mont., discontinued as port of entry for aliens	1947
--	------

TITLE 16—COMMERCIAL PRACTICES: Federal Trade Commission: Quality Bakers of America et al., cease and desist order	1948
--	------

TITLE 21—FOODS AND DRUGS: Food and Drug Administration: Coal-tar colors suitable for use in foods, etc., regula- tions for listing of	1922
---	------

(Continued on next page)

1921



Published by the Division of the Federal Register, The National Archives, pursuant to the authority contained in the Federal Register Act, approved July 26, 1935 (49 Stat. L. 500), under regulations prescribed by the Administrative Committee, with the approval of the President.

The Administrative Committee consists of the Archivist or Acting Archivist, an officer of the Department of Justice designated by the Attorney General, and the Public Printer or Acting Public Printer.

The daily issue of the FEDERAL REGISTER will be furnished by mail to subscribers, free of postage, for \$1 per month or \$10 per year; single copies 10 cents each; payable in advance. Remit by money order payable to Superintendent of Documents, Government Printing Office, Washington, D. C.

Correspondence concerning the publication of the FEDERAL REGISTER should be addressed to the Director, Division of the Federal Register, The National Archives, Washington, D. C.

#### CONTENTS—Continued

<b>TITLE 24—HOUSING CREDIT:</b>	
Federal Home Loan Bank Board:	Page
Federal Savings and Loan System, disposition of mortgages on same real estate	1949
<b>Home Owners' Loan Corporation:</b>	
Fees, limitation on	1949
<b>TITLE 31—MONEY AND FINANCE:</b>	
<b>TREASURY:</b>	
Public Debt Service:	
Offering of Home Owners' Loan Corporation 3 1/8% and 5 1/8% bonds	1949
<b>NOTICES</b>	
Civil Aeronautics Authority:	
Air travel card plan, investigation and hearing	1954
Continental Air Lines, Inc., hearing	1954
New York World's Fair of 1939, traffic rule amended	1953
Department of Labor:	
Division of Public Contracts:	
Cereal-Preparations Industry, hearing on determination of prevailing minimum wages	1952
Wage and Hour Division:	
Definitions amended:	
"Hat industry"	1953
"Millinery industry"	1953
Hat Industry, notice of hearing on minimum wage rates	1953
Federal Power Commission:	
Liversidge, Horace P., hearing	1954
Securities and Exchange Commission:	
International Utilities Corp., hearing	1955

#### CONTENTS—Continued

Treasury Department:	
Bureau of Customs:	Page
Wellesley Farms Airport and Wellesley Island Seaplane Base, N. Y., redesignated airports of entry	1950
Federal Alcohol Administration Division:	
Credit period to be extended to retailers of alcoholic beverages (digest of interpretations of Regulations No. 8)	1950

Independence of the United States of America the one hundred and sixty-third.

FRANKLIN D ROOSEVELT

By the President:

CORDELL HULL

Secretary of State.

[No. 2335]

[F. R. Doc. 39-1549; Filed, May 6, 1939; 1:00 p. m.]

#### Rules, Regulations, Orders

#### TITLE 21—FOOD AND DRUGS

##### FOOD AND DRUG ADMINISTRATION

IN THE MATTER OF PUBLIC HEARING FOR PURPOSE OF RECEIVING EVIDENCE UPON BASIS OF WHICH REGULATIONS MAY BE PROMULGATED FOR LISTING OF COAL-TAR COLORS WHICH ARE HARMLESS AND SUITABLE FOR USE IN FOODS, DRUGS, AND COSMETICS, DRUGS AND COSMETICS, AND EXTERNALLY APPLIED DRUGS AND COSMETICS; FOR CERTIFICATION OF BATCHES OF SUCH COLORS; FOR PROCEDURES THEREUNDER; AND FOR PAYMENT OF FEES THEREFOR

##### ORDER OF THE SECRETARY PROMULGATING REGULATIONS EFFECTIVE ON PUBLICATION

Pursuant to, and under and by virtue of, the authority and direction of the Federal Food, Drugs, and Cosmetic Act (Sec. 701, 52 Stat. 1055; 21 U.S.C. 371 (e); Sec. 406 (b), 52 Stat. 1049; 21 U.S.C. 346 (b); Sec. 504, 52 Stat. 1052; 21 U.S.C. 354; Sec. 604, 52 Stat. 1055; 21 U.S.C. 364; Sec. 706, 52 Stat. 1058; 21 U.S.C. 376), and based upon substantial evidence of record at the hearing<sup>1</sup> in the above-entitled matter, detailed findings of fact are made, as follows:

##### Findings of Fact

1

Coal-tar colors—Derivation—scope of term. That coal-tar colors are materials consisting of one or more substances which either are made from coal-tar, or are capable of derivation from intermediates of the same identity as coal-tar

intermediates. They include all substances from these sources which are themselves colored and impart their color to the substance to which they are applied, and they also include those compounds which do not themselves possess the color imparted to the substance to which they are applied but which, when applied to such substance, impart color. (For example: Orange I is prepared from coal-tar intermediates. It is itself colored and imparts color when applied to a substance. Alizarin may be made either from coal-tar intermediates or from the root of the madder plant. It is colored and imparts color and is considered a coal-tar color whether derived from coal-tar or from a natural source. Paraphenylenediamine is colorless but is considered a coal-tar color, since it is derived from coal-tar and imparts color when applied to other substances.) Coal-tar colors may also include diluents or substrata. In the manufacture of coal-tar colors all impurities are not completely eliminated.

2

Definitions of terms used in regulations. That the following technical terms when used in connection with any coal-tar colors, hereinafter referred to, are found to mean:

(1) A "straight color" is a coal-tar color listed in Sections 135.03, 135.04, or 135.05 of the regulations hereby promulgated (formerly Section 35.02), and includes such impurities and substrata as are contained in such color.

(2) The term "mixture" when applied to a coal-tar color means a coal-tar color made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(3) A "diluent" is any component of a coal-tar color except a straight color.

(4) The expression "pure dye" refers exclusively to the coal-tar dye contained in a coal-tar color. It does not include any intermediate, impurity, diluent, substratum, or any material other than the coal-tar dye contained in a coal-tar color.

(5) "Substratum" is the substance on which the pure dye in a lake is extended.

(6) The term "alumina" means a suspension in water of precipitated aluminum hydroxide.

(7) The term "blanc fixe" means a suspension in water of precipitated barium sulfate.

(8) "Gloss white" means a suspension in water of coprecipitated aluminum hydroxide and barium sulfate.

(9) The term "mixed oxides" means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color), calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(10) A "batch" is a quantity of coal-tar color prepared or mixed by the manufacturer or person requesting certifica-

tion and held intact for the purpose of receiving certifications.

(11) A "batch number" is an identification number assigned to a batch of coal-tar color by the person requesting certification.

(12) A "lot number" is an identification number assigned to a batch of coal-tar color by the Food and Drug Administration upon certification of such batch.

(13) The expression "externally applied drugs and cosmetics" refers to those drugs and cosmetics which are applied to the external parts of the body and not to the lips or to any body surface covered by mucous membrane and does not include any drugs or cosmetics which are taken internally.

3

*No coal-tar color in the orbital area.* That coal-tar colors are not harmless for use in preparations applied to the area of the eye, which means the area bounded by the supra-orbital ridge and the infra-orbital ridge, including the eye, the skin below the eyebrow, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge. The application of coal-tar colors to this area may cause serious injury and even loss of sight. No coal-tar color should be certified for use in a product to be applied to the area of the eye. A coal-tar color used in a product to be applied to this area should be considered to be from a batch that has not been certified, even though such color is from a batch that has been certified for other use.

4

*Section 201 of Federal Food, Drug, and Cosmetic Act applicable.* That the definitions and interpretations of terms contained in Section 201 of the Federal Food, Drug, and Cosmetic Act should be made applicable also to such terms when used in regulations for the listing of coal-tar colors, certification of batches thereof, and payment of fees for such service.

5

*Derived from coal-tar or synthesized.* That coal-tar is derived from coal, and that coal-tar colors are synthesized from coal-tar derivatives. The coal-tar colors listed in Sections 135.03, 135.04 and 135.05 of the regulations hereby promulgated (formerly Section 35.02) are derived from intermediates of coal-tar origin, or from synthesized intermediates possessing the same chemical identity. Coal-tar intermediates are products, resulting from a destructive distillation of coal followed by a purification of the coal-tar, formed during such distillation.

6

*Coal-tar colors—common names—technical names—specifications.* That the colors listed in Sections 135.03, 135.04 and 135.05 of the regulations hereby pro-

mulgated (formerly Section 35.02), and each of them, are designated, first, with a common name, second, with a scientific name or technical description, and third, specifications limiting the amount of impurities that cannot be avoided in good manufacturing practice.

7

*Technical name.* That the technical descriptions and the specifications for purity serve to identify the colors qualitatively and quantitatively.

8

*Colors grouped according to use.* It is found that the colors listed in Sections 135.03, 135.04 and 135.05 of the regulations hereby promulgated (formerly Section 35.02), are properly listed in three essential subdivisions, namely those colors entitled to certification for use in foods, drugs, and cosmetics, those colors entitled to certification for use in drugs and cosmetics, and those colors entitled to certification for use in externally applied drugs and cosmetics. It is further found that no coal-tar color should be listed for certification unless it is harmless and suitable for the use for which it is listed.

9

*New system for common names—grouping.* That the common names heretofore used for the colors listed in Sections 135.03, 135.04 and 135.05 of the regulations hereby promulgated (formerly Section 35.02) are not adequate for the purposes of such regulations; that a new system of common names should be established, such names to show: (1) the use for which the color is permitted, (2) the predominant shade of the color, and (3) the number distinguishing the color from others of the same shade, permitted for the same use. Under such system the prefix "FD&C" would indicate that the color is harmless and suitable for use in foods, drugs and cosmetics; the prefix "D&C" that the color is harmless and suitable for use in drugs and cosmetics, but not in foods; and the prefix "Ext D&C" that the color is harmless and suitable for use only in externally applied drugs and cosmetics.

10

*Straight colors—certification.* That batches of straight colors should be certified in accordance with the provisions of the regulations hereby promulgated for use in food, drugs, and cosmetics, when batches of such colors meet the specifications to be enumerated in such regulations.

11

*Colour index abandoned.* That with reference to the Colour Index of 1924 published by the Society of Dyers and Colourists of England, the utilization of numbers assigned in this publication to certain colors, is confusing and misleading when these numbers are applied to colors listed in the regulations hereby

promulgated. These numbers should not, therefore, appear in the regulations, and neither should there appear any reference whatever to the said Colour Index of 1924.

12

*Descriptive chemical name—system of American Chemical Society.* It is found that a uniform system of nomenclature has not heretofore been used in assigning the technical descriptions or names to these colors. It is found as a fact that a uniform system of nomenclature in assigning technical names should be used in and throughout the regulations hereby promulgated; and that the system of nomenclature adopted by the American Chemical Society should be followed in assigning a technical description, or name, to each of the coal-tar colors listed in such regulations, and also to any coal-tar color that may be subsequently added to those listed in such regulations.

13

*Straight coal-tar colors.* That a straight color should be free from all impurities (other than those hereinafter named in specifications, in amounts found to be harmless and suitable for use) to the extent that such impurities can be avoided in good manufacturing practice.

14

*Restricted use.* That the coal-tar colors listed in Sections of the regulations hereby promulgated are harmless and suitable for the restricted uses indicated in such regulations, if they meet the general specifications set up in Section 135.02 of such regulations, together with the individual specifications for the respective colors as listed in Sections 135.03, 135.04 and 135.05 of such regulations.

15

*(Guinea Green B) FD&C Green No. 1.* That the common name of the first color listed in Section 135.03 of the regulations hereby promulgated under the new nomenclature would be FD&C Green No. 1. The technical description of this color would be "Monosodium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)-diphenylmethylene]-[1-(N-ethyl-N-p-sulfonium-benzyl)- $\Delta^2$ -cyclohexadienimine]."

16

*FD&C Green No. 1—Volatile matter.* That the first specification that appears after the technical name of the color FD&C Green No. 1, is "Volatile matter (at 135° C.), not more than 10.0 percent." Volatile matter, consists largely of moisture, but the term also includes any other materials which evaporate when the color is heated to 135° C. The limitation of 10.0% is practicable in good manufacturing practice. A more strict limitation of volatile matter might produce a color so dry as to be difficult to handle and to maintain in the condition

in which it is manufactured. Said color with such specification is found to be harmless and suitable for use in foods, drugs, and cosmetics.

17

**FD&C Green No. 1—Water insoluble matter.** That FD&C Green No. 1, the second specification which appears after the technical name is "Water insoluble matter, not more than 0.5 percent." This color is a water soluble color and, therefore, any material contained therein which is not soluble in water is an impurity. This specification is reasonable, practicable and necessary to insure the purity of the color, and with the limitation designated this color is found to be harmless and suitable for use in foods, drugs, and cosmetics.

18

**FD&C Green No. 1—ether extracts.** The next specification under said color FD&C Green No. 1 is "Ether extracts, not more than 0.4 percent." This specification is practicable in good manufacturing practice. The ether extracts measure the amount of uncombined intermediates present in the color. All intermediates cannot be completely removed from this or any color, and the specification of 0.4 percent for this color is a reasonable specification which, when followed, will render the color harmless and suitable for use in foods, drugs, and cosmetics.

19

**FD&C Green No. 1—chlorides and sulfates.** That the fourth specification that appears after the technical name of FD&C Green No. 1, is "Chlorides and sulfates of sodium, not more than 6.0 percent." Chlorides and sulfates are salts that are either added or formed during the process of manufacturing. The limit of 6.0 percent is practicable in good manufacturing practice. It is found that this specification is a satisfactory one that does not render the color harmful or unsuitable for use in foods, drugs, and cosmetics.

20

**FD&C Green No. 1—mixed oxides.** That the fifth specification that appears after the technical name of FD&C Green No. 1, is "Mixed oxides, not more than 1.0 percent." The impurities "mixed oxides" need not be present in amounts greater than 1.0% if good commercial practice is followed in the manufacture of the color. This limitation is found to be proper and practicable and does not render the color harmful or unsuitable for use in foods, drugs, and cosmetics.

21

**FD&C Green No. 1—lead (as Pb.).** That the sixth specification that appears after the technical name of FD&C Green No. 1, is "Lead (as Pb), not more than 0.001 percent." The specification "Lead (as Pb), not more than 0.001 per-

cent" is practicable in good manufacturing practice. The basis for the small amount of lead, as stated in the specification for the above color, is the background of medical opinion concerning the toxicity of lead and the opinion held generally by scientists particularly qualified to be familiar with the toxicity of lead, all of which appears in and has been comprehensively dealt with in medical and scientific literature. A larger percentage of lead in a coal-tar color to be used in foods, drugs, and cosmetics, might be dangerous to the health of the user. Our natural foodstuffs contain lead, and thus we cannot get away from the ingestion of this poison in small amounts. To avoid adding substantially more lead to the daily intake, the amount of lead in coal-tar colors for use in foods should be held to a minimum. The effect of lead taken internally is the same with respect to foods, drugs, and cosmetics. Lead contained in cosmetics can be absorbed through the skin to which the cosmetic is applied, and after such lead enters into the system, it is capable of producing the same systemic effects as when ingested. Lead has no known function in living tissue. It is found that this specification does not render the color harmful or unsuitable for use in foods, drugs or cosmetics.

22

**FD&C Green No. 1—arsenic (as As<sub>2</sub>O<sub>3</sub>).** That the seventh specification that appears after the technical name of FD&C Green No. 1, is "Arsenic (as As<sub>2</sub>O<sub>3</sub>), not more than 0.00014 percent." This specification is practicable in good manufacturing practice. In the percentage named, this poisonous substance has been reduced to an infinitesimal and comparatively harmless proportion. Arsenic is capable of being accumulated in the system. It also has a cumulative effect. It may effect the liver, the peripheral nervous system, the blood-forming organs, or the blood system. Arsenic, when applied to the skin, is capable of causing a carcinomatous condition of the skin. The presence of arsenic in any coal-tar color that is to be used in any food, drug, or cosmetic, should be kept at the lowest possible minimum. It is found that this specification does not render the color harmful or unsuitable for use in foods, drugs or cosmetics.

23

**FD&C Green No. 1—heavy metals.** That the eighth specification after the technical name of FD&C Green No. 1, is "Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace". It is practicable to restrict impurities of this nature to a mere trace in good manufacturing practice. The proposed specification is reasonable. The term "trace" means below any figure that could be quantitatively determined. It is found that this specification does not render the color harmful or unsuitable for use in foods, drugs or cosmetics.

24

**FD&C Green No. 1—pure dye.** That the ninth and last specification after the technical name of FD&C Green No. 1, is "Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent." This specification is practicable in good manufacturing practice and will not render the color harmful or unsuitable for use in foods, drugs or cosmetics.

25

**Findings applicable to same or similar specifications for other coal-tar colors.** That the preceding findings of fact with reference to the specifications under FD&C Green No. 1, dealing with volatile matter, water insoluble matter, ether extracts, chlorides and sulfates of sodium, mixed oxides, lead (as Pb), arsenic, heavy metals, and pure dye, are equally applicable to each of these same specifications wherever they subsequently appear in any of the colors listed in the regulations hereby promulgated, and the facts stated as a basis for the adoption of such specifications for FD&C Green No. 1, are hereby specifically found to be applicable to each and every one of the said colors listed in such regulations in every instance wherever such specifications appear; and where such specifications do appear and it is found that the numerical limitations therein given such specifications are necessary to insure the purity, harmlessness and suitability for use of the colors listed for the restricted purposes for which they are to be used, that such specifications heretofore found to be necessary for the color FD&C Green No. 1, are equally necessary to the color subsequently listed wherever said specifications appear in such regulations irrespective of the fact that such specifications provide in some instances a different numerical limit necessary for the particular color, and that said numerical limits are different from those stated in the specifications found to be harmless and suitable for use in the color FD&C Green No. 1.

26

**Lakes should be grouped and segregated—composite specifications.** That individual lakes should be consolidated so as to have master specifications that are a composite of all of the specifications that have been set up under each of the said lakes, all of which said specifications should be available for use in the manufacture of any of the said lakes; that the systems of nomenclature, hereinbefore adopted in the foregoing findings of fact both with respect to common and technical names, should be applied to all lakes hereby or hereafter listed for certification for use in drugs and cosmetics, and externally applied drugs and cosmetics, in exactly the same manner as they are applied to other straight colors that are hereby or that may hereafter be listed for certification for use in foods, drugs, and cosmetics.

27

(Light Green SF Yellowish) *FD&C Green No. 2.* That the common name of this color should be *FD&C Green No. 2* and the technical description should be "Disodium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl]-[4-sulfoniumpheyl]-methylene)-[1-(N-ethyl-N-p-sulfobenzyl- $\Delta^{2,5}$ -cyclohexadienimine)]. The remaining specifications of this color, except the specification "subsidiary dyes (as Guinea Green B) not more than 5.0 percent, were all found to be necessary, proper and practicable specifications for the color *FD&C Green No. 1*, and are hereby found to be also necessary and proper specifications for the color *FD&C Green No. 2*. The Specification "subsidiary dyes (as Guinea Green B) not more than 5.0 percent" should be changed to "subsidiary dyes (as *FD&C Green No. 1*) not more than 5.0 percent." The said color, with its specifications, is found to be harmless and suitable for use in food, drugs, and cosmetics.

28

(Fast Green FCF) *FD&C Green No. 3.* That the common name of this color should be *FD&C Green No. 3* and the technical description should be "Disodium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl]-[4-hydroxy-2-sulfoniumpheyl]-methylene)-[1-(N-ethyl-N-p-sulfobenzyl- $\Delta^{2,5}$ -cyclohexadienimine]). Its specifications are all found to be appropriate and practicable in good manufacturing practice; and said color is found to be harmless and suitable for use in foods, drugs, and cosmetics.

29

(Naphthol Yellow S) *FD&C Yellow No. 1.* That the common name of this color should be *FD&C Yellow No. 1*, and the technical description should read: "Disodium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid." The specifications for such color, with the exception of "Martius Yellow, not more than 0.03 percent" have heretofore all been found to be appropriate and practicable in good manufacturing practice for use in other colors; and the findings of fact made with respect to such specifications previously given, are hereby incorporated in this finding and made a part hereof. The specification "Martius Yellow, not more than 0.03 percent" deals with the unsulfonated toxic substance which remains in the finished product *FD&C Yellow No. 1*; that the proposed limitation is practicable in good manufacturing practice. It is found that if not more than 0.03 percent of Martius Yellow is contained in this color it will be harmless and suitable for use in food, drugs, and cosmetics.

30

(Naphthol Yellow S—Potassium Salt) *FD&C Yellow No. 2.* That the common name of this color should be *FD&C*

Yellow No. 2, and the technical description should be "Dipotassium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid." The remaining specifications for this color having been previously found to be appropriate for other colors, this color is found to be harmless and suitable for use in foods, drugs, and cosmetics.

31

(Yellow AB) *FD&C Yellow No. 3.* That the common name of this color should be *FD&C Yellow No. 3*, and the technical description should be "1-phenylazo-2-naphthylamine." In this color there are a number of specifications concerning which findings have not heretofore been made. The first of these specifications is "Sulfated ash, not more than 0.3 percent." Sulfated ash is a measure of inorganic impurities, a form of impurity which cannot be entirely eliminated in the manufacturing process. The next two specifications not previously referred to in the preceding findings of fact are "water soluble matter, not more than 0.3 percent" and "matter insoluble in carbon tetrachloride, not more than 0.5 percent." Said specifications are practicable in good manufacturing practice and necessary to insure the purity of the color. The next specification which has not been referred to in the preceding findings of fact, deals with uncombined intermediates. A limitation of 0.05 percent is reasonable and practicable in good manufacturing practice. The next specification that has not been referred to in the preceding findings of fact, is "melting point, not less than 99° C." The melting point gives a partial identification of the color and also serves as a good indication of its purity. The necessity for the remaining specifications for this color has previously been referred to in preceding findings of fact, all of which are applicable here. The said color with its specifications is found to be harmless and suitable for use in foods, drugs, and cosmetics.

32

(Yellow OB) *FD&C Yellow No. 4.* That the common name of this color should be *FD&C Yellow No. 4*, and the technical description should be "1-o-tolylazo-2-naphthylamine." All of the remaining specifications have been referred to in previous findings of fact, which said specifications all occurred under other colors. It is found that this color with its specifications is harmless and suitable for use in foods, drugs, and cosmetics.

33

(Tartrazine) *FD&C Yellow No. 5.* That the common name of this color should be *FD&C Yellow No. 5*, and the technical description should be "trisodium salt of 3-carboxy-5-hydroxy-1-p-sulfophenyl-4-p-sulfophenylazo-pyrazole." The specification for "phenylhydrazine-p-sulfonic acid, not more than 0.1 percent," discloses that this substance

is an intermediate used in the manufacture of this color, and that the specification is necessary in order to limit the amount of this impurity to a figure which will permit the color to be used in foods, drugs, and cosmetics. This specification and the remaining ones, all of which have been previously referred to in preceding findings of fact, are found to be such that they will not render the color harmful or unsuitable for use in foods, drugs, and cosmetics.

34

(Sunset Yellow FCF) *FD&C Yellow No. 6.* That the common name of this color should be *FD&C Yellow No. 6*, and the technical description should be "disodium salt of 1-p-sulfophenylazo-2-naphthol-6-sulfonic acid." The remaining specifications set up for said color have all previously been referred to in the preceding findings of fact and are hereby found to be within proper limitations to entitle this color to be listed as harmless and suitable for use in foods, drugs, and cosmetics.

35

(Ponceau 3R) *FD&C Red No. 1.* That the common name of this color should be *FD&C Red No. 1*, and the technical description should read "disodium salt of 1-pseudocumylazo-2-naphthol-3,6-disulfonic acid." The specification "pseudocumidine, not more than 0.2 percent," has not been referred to in the preceding findings of fact. Pseudo-cumidine is an intermediate used in manufacture of this color and the amount present should not exceed the limit stated in the proposed specifications, which is practicable in good manufacturing practice. The next specification not previously referred to in the preceding findings is "lower sulfonated dyes, not more than 5.0 percent." This specification deals with dyes which are related to *FD&C Red No. 1*. Manufacturers can meet the figure stated. The next specification not previously referred to in the preceding findings of fact, is "boiling range of crude pseudo-cumidine, or of pseudo-cumidine obtained by reduction of the dye, 220-245° C." This specification is practicable in good manufacturing practice and is necessary in order to insure the uniformity of different batches of this color which may be submitted for certification. The remaining specifications, all of which have previously been referred to in preceding findings of fact for other colors, are found to be necessary for this color in the figures stated and will not render this color harmful or unsuitable for use in foods, drugs and cosmetics.

36

(Amaranth) *FD&C Red No. 2.* That the common name of this color should be *FD&C Red No. 2*, and the technical description should read "Trisodium salt of 1-(4-sulfo-1-naphthylazo)-2-naphthol-3,6-disulfonic acid." The remaining specifications have previously been approved for other colors in the preced-

ing findings of fact and it is found that the color with its specifications is harmless and suitable for use in foods, drugs, and cosmetics.

37

(Erythrosine) FD&C Red No. 3. That the common name of this color should be FD&C Red No. 3, and the technical description should read "disodium salt of 9-o-carboxyphenyl-6-hydroxy-2,4,5,7-tetraiodo-3-isoxanthone." The specification "sodium carbonate, not more than 0.5 percent" and the specification "sodium iodide, not more than 0.4 percent" have not previously been referred to in the preceding findings of fact. These specifications are practicable in good manufacturing practice. Another specification not previously referred to in the preceding findings of fact with reference to any color is "permitted range of organically combined iodine in pure dye, 52.5-54.5 percent." To avoid ambiguity, this specification should be changed to read "permitted range of organically combined iodine in pure dye, free from water of crystallization, 56.8 to 58.5 percent." This tolerance is practicable in good manufacturing practice. The remaining specifications having been approved in preceding findings of fact with respect to other colors, are hereby found to be harmless and necessary for this color. The said color with its specifications is hereby found to be harmless and suitable for use in foods, drugs, and cosmetics.

38

(Ponceau SX) FD&C Red No. 4. That the common name of this color should be FD&C Red No. 4, and the technical description should read "disodium salt of 2-(5-sulfo-2,4-xylylazo)-1-naphthol-4-sulfonic acid." All of the specifications for said color having been previously referred to in the preceding findings of fact as being appropriate for use under other colors, are found to be appropriate for use under this color and the said color with its specifications, is found to be harmless and suitable for use in foods, drugs, and cosmetics.

39

(Orange I) FD&C Orange No. 1. That the common name of this color should be FD&C Orange No. 1, and the technical description should read "Monosodium salt of 4-p-sulfo-phenylazo-1-naphthol." "Alpha-Naphthol, not more than 0.1 percent" is a specification not previously referred to in connection with any other color. This specification is practicable in good manufacturing practice. The specification "Orange II (151), not more than 5.0 percent" is referred to in this instance for the first time. This specification is practicable in good manufacturing practice. The parenthetical statement "(151)" which appears in this specification should be deleted. The remaining specifications, all of which have been referred to in connection with other colors in the preceding findings of fact, are all

found to be appropriate for this color. The color is found to be harmless and suitable for use in foods, drugs, and cosmetics.

40

(Orange SS) FD&C Orange No. 2. That this color should be listed under the common name FD&C Orange No. 2, and the technical description should read "1-o-Tolylazo-2-naphthol." A specification not previously referred to and approved for colors in this group in the preceding findings of fact, is "o-Toluidine, not more than 0.05 percent." Another specification not previously referred to and approved in the preceding findings of fact is "beta-naphthol, not more than 0.05 percent." The specifications for o-Toluidine and beta-naphthol are reasonable and practicable in good manufacturing processes. The remaining specifications for this color have been previously found to be suitable for other colors. They are also found to be necessary, proper and practicable for this color. The said color, with its specifications, is found to be harmless and suitable for use in foods, drugs, and cosmetics.

41

(Brilliant Blue FCF) FD&C No. 1. That this color should be listed under the common name FD&C Blue No. 1, and the technical description should read "Disodium salt of 4-((4-(N-ethyl-p-sulfobenzylamino)-phenyl)-(2-sulfoniumpheyl)-methylene)-[1-(N-ethyl-N-p-sulfo-benzyl)- $\Delta^{2,5}$ -cyclohexadienimine]." The only specification under this color not previously found to be appropriate is "sodium acetate, not more than 3.0 percent." This specification is practicable in good manufacturing practices. The remainder of these specifications have been referred to in the preceding findings of fact with reference to other colors. The said color with its specifications is found to be harmless and suitable for use in foods, drugs and cosmetics.

42

Indigotine) FD&C Blue No. 2. That the common name of this color should be FD&C Blue No. 2. The technical description should read "Disodium salt of 5,5'-indigotindisulfonic acid." The remaining specifications for this color, all of which have been previously referred to in the preceding findings of fact in connection with other colors, are hereby found to be necessary and the said color with the specifications as aforesaid, is found to be harmless and suitable for use in foods, drugs, and cosmetics.

43

*Lakes combined and grouped according to use.* That all the coal-tar colors in which the word "Lake" appears in the common name, and in which the said word "Lake" is qualified, by one of the following words: "Aluminum," "Barium," "Calcium," "Strontium," "Zirconium," "Sodium," or "Madder," should be com-

bined and segregated into two groups, and each group should be covered by a master specification conditioned upon the purposes for which such colors are to be listed and certified for use; that for one of said groups there should be specifications for all those lakes which are harmless and suitable for use in drugs and cosmetics, and for the other group all those colors which are harmless and suitable for use in externally applied drugs and cosmetics.

44

(Light Green CF Yellowish) D&C Green No. 4. That the common name of this color should be D&C Green No. 4. The technical description should read "Calcium salt of 4[(4-(N-ethyl-p-sulfobenzylamino)-phenyl)-(4-sulfonium-phenyl)-methylene]-1-[(N-ethyl-N-p-sulfonylbenzyl)- $\Delta^{2,5}$ -cyclohexadienimine]." Under "Specifications" is found "Oxides of iron and aluminum, not more than 1.0 percent." This limitation is practicable in good manufacturing practice. The remaining specifications of this color have been previously referred to in preceding findings of fact and this color is found to be harmless and suitable for use in drugs and cosmetics.

45

(Alizarin Cyanine Green F) D&C Green No. 5. That the common name of this color should be D&C Green No. 5 and the technical description should read "Disodium salt of 1,4-bis(o-sulfo-p-tolueno)-anthraquinone." It is found that the specification "1:4-Dichloro-anthraquinone, not more than 0.2 percent" is for an intermediate no longer used in the manufacture of the color and that the intermediate now used in the manufacture of the color, "1:4-Di-hydroxy-anthraquinone," should be substituted in the original specification. The remaining specifications, all of which have been referred to in preceding findings of fact with respect to other colors, are appropriate for use with this color and the color with all of its specifications is found to be harmless and suitable for use in drugs and cosmetics.

46

(Quinizain Green SS) D&C Green No. 6. That the common name of this color should be D&C Green No. 6 and the technical description should read "1,4-Bis (p-tolueno)-anthraquinone." All of the specifications under this color have been referred to in the preceding findings of fact with respect to other colors and this color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

47

(Fluorescein) D&C Yellow No. 7. That the common name of this color should be "D&C Yellow No. 7" and the technical description should read "3,6-Fluorandiol." This color has two specifications that have not previously been referred to in connection with any

other color. The first specification is "Insoluble matter (alkaline solution), not more than 1.0 percent." The second specification is "Ether extract (from alkaline solution), not more than 0.5%." These tolerances are practicable in good manufacturing practice. The remaining specifications for this color have been previously referred to in preceding findings of fact under other colors, and this color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

48

(Uranine) *D&C Yellow No. 8.* That the common name of this color should be *D&C Yellow No. 8* and the technical description should be "Disodium salt of 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." The specifications for this color are found to be appropriate with the exceptions that the specification for "Insoluble matter" should read "Water insoluble matter, not more than 1.0 percent" and that for "ether extracts" should read "Ether extracts, not more than 0.5 percent." The parenthetical specification "(alkaline solution)" and "(from alkaline solution)" should be eliminated. The remaining specifications have been previously referred to in preceding findings of fact with respect to other colors; and this color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

49

(Uranine K) *D&C Yellow No. 9.* That the common name of this color should be *D&C Yellow No. 9* and the technical description should read "Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." With the exception that the specifications reading "Insoluble matter (alkaline solution), not more than 1.0 percent" and "Ether extracts (from alkaline solution), not more than 0.5 percent" should be "Water insoluble matter, not more than 1.0 percent" and "Ether extracts, not more than 0.5 percent," the specifications, for said color are found to be appropriate and the color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

50

(Quinoline Yellow WS) *D&C Yellow No. 10.* That the common name of this color should be *D&C Yellow No. 10* and the technical description should read "Disodium salt of disulphonic acid of 2-(2-quinolyl)-1, 3-indandione." This color contains a specification for "Quinaldine, not more than 0.2%" that has not previously been referred to in any other preceding findings of fact. The proposed limitation is practicable in good manufacturing practice. The remaining specifications for this color are found to be appropriate and the said color, with said specifications, is found to be harmless and suitable for use in drugs and cosmetics.

51

(Ponceau 2R) *D&C Red No. 5.* That the common name of this color should be "*D&C Red No. 5*" and the technical description should be "Disodium salt of 1-xylylazo-2-naphthol-3, 6-disulfonic acid." The only specification not previously referred to in connection with some other color is "Xyldine, not more than 0.2 percent." The above proposed specification is practicable in good manufacturing practice. The remaining specifications for this color have previously been referred to in preceding findings of fact, and it is found that this color, with its specifications, is harmless and suitable for use in drugs and cosmetics.

52

(Lithol Rubin B) *D&C Red No. 6.* That the common name of this color should be *D&C Red No. 6* and the technical description should read "Monosodium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid." One of the specifications for this color, "Ether extracts (isopropyl ether), not more than 0.5%" has not previously been referred to in the preceding findings of fact under any other color. The proposed specification is practicable in good manufacturing processes. The remaining specifications have been referred to in preceding findings of fact under other colors and this color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

53

(Lithol Rubin BCA) *D&C Red No. 7.* That the common name of this color should be *D&C Red No. 7* and the technical description for this color should read "Calcium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid." The specifications for this color are found to be necessary and the said color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

54

(Lake Red C) *D&C Red No. 8.* That the common name of this color should be *D&C Red No. 8* and the technical name for this color should read "Sodium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-naphthol." With the exception of "Lake Red C Amine, not more than 0.2 percent," all of the specifications for said color have been previously referred to in preceding findings of fact and the same are hereby found to be necessary for this color. The said specification "Lake Red C Amine, not more than 0.2 percent," is practicable in good manufacturing practice. The said color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

55

(Lake Red CBA) *D&C Red No. 9.* That the common name of this color should be "*D&C Red No. 9*" and the technical description should read "Barium salt of 2-(hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid." The specifications for this color have been previously referred to in preceding findings of fact under other colors and are found

thol." All of the specifications for this color with the exception of one have been previously referred to in preceding findings of fact with respect to other colors. This one specification that has not been previously referred to is "Soluble barium in dilute HCl (as BaCl<sub>2</sub>), not more than 0.05 percent." Barium has some very peculiar stimulating and irritating effects upon the cells of the body and is a specific and peculiar cellular poison. Barium should be kept at the lowest possible level in all substances taken into or brought in contact with the body in order to avoid producing injuries. If barium is restricted to the amount in this specification, no possible harm would result from the use of the color for the restricted purposes indicated. This is likewise true of other colors that contain barium. This finding with respect to soluble barium is expressly made applicable to all of the colors listed in the regulations hereby promulgated. All of the remaining specifications for the color have been previously referred to in preceding findings of fact relating to the specifications for other colors, and this color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

56

(Lithol Red) *D&C Red No. 10.* That the common name of this color should be *D&C Red No. 10* and the technical description should appear as "Monosodium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalene-sulfonic acid." Among the specifications for said color is one that has not previously been discussed in any of the preceding findings of fact under any other color. This specification is "Tobias acid, not more than 0.2 percent." The limit prescribed is practicable in good manufacturing practice. The remainder of the specifications for this color have in previous findings of fact been found to be appropriate, and the said color with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

57

(Lithol Red CA) *D&C Red No. 11.* That the common name of this color should be *D&C Red No. 11*, and the technical description should be "Calcium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid." The specifications for this color are found to be entirely appropriate and the color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

58

(Lithol Red BA) *D&C Red No. 12.* That the common name of this color should be *D&C Red No. 12*, and the technical description should be "Barium salt of 2-(hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid." The specifications for this color have been previously referred to in preceding findings of fact under other colors and are found

to be appropriate for use with this color. The said color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

59

(Lithol Red SR) *D&C Red No. 13.* That the common name of this color should be D&C Red No. 13, and the technical description should be "Strontium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid." The specifications, for this color, have been referred to in preceding findings of fact with respect to other colors. These specifications are found to be appropriate for this color and the said color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

60

(Lake Red D) *D&C Red No. 14.* That the common name of this color should be D&C Red No. 14, and the technical description should be "Monosodium salt of 1-o-carboxyphenylazo-2-naphthol." The specifications for this color are found to be appropriate for this color. All these specifications have been referred to in preceding findings of fact under other colors. This color with its said specifications is found to be harmless and suitable for use in drugs and cosmetics.

61

(Lake Red DBA) *D&C Red No. 15.* That the common name of this color should be D&C Red No. 15, and the technical description should be "Barium salt of 1-o-carboxyphenylazo-2-naphthol." The specifications for this color are found to be appropriate as they have been referred to as being suitable for use in other colors in preceding findings of fact. The said color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

62

(Lake Red DCA) *D&C Red No. 16.* That the common name of this color should be D&C Red No. 16, and the technical description should be "Calcium salt of 1-o-carboxyphenylazo-2-naphthol." The specifications for this color are found to be appropriate as they have been referred to as being suitable for use in other colors in preceding findings of fact. The said color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

63

(Toney Red) *D&C Red No. 17.* That the common name of this color should be D&C Red No. 17, and the technical description of this color should be "1-p-Phenylazophenylazo-2-naphthol." This color has a specification for "Insoluble matter (in tolene), not more than 3.0 percent" that has not been referred to in connection with the specifications of any of the other colors in the preceding findings of fact. This speci-

fication is practicable in good manufacturing practice. Another specification not referred to in connection with any other color in the preceding findings of fact is "Amino-azo-benzene, not more than 0.2 percent." This impurity should be restricted to not more than 0.2 percent as is practicable in good manufacturing processes. The remaining specifications for this color have been referred to in preceding findings of fact, and they are found to be appropriate for this color also. The color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

64

(Oil Red OS) *D&C Red No. 18.* That the common name of this color should be D&C Red No. 18, and the technical description should be "1-Xylylazoxylylazo-2-naphthol." One specification for this color has not been discussed with respect to any other color in the preceding findings of fact. This specification is "Amino-azo-xylene, not more than 0.2 percent." Said tolerance is practicable in good manufacturing practice. The remaining specifications have been previously referred to and approved for other colors, and are found appropriate for this color. The said color with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

65

(Rhodamine B) *D&C Red No. 19.* That the common name of this color should be D&C Red No. 19, and the technical description should be "3-Ethochloride of 9-o-carboxyphenyl-6-diethylamino-3-ethylimino-3-isoxanthene." That the specification for "Ether extracts, not more than 0.5 percent," should read "Ether extracts (from acid solution), not more than 0.5 percent." All of the specifications for this color have been referred to and approved for use with other colors, and are found to be appropriate for this color with the exception of the change mentioned. The said color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

66

(Rhodamine B-Acetate) *D&C Red No. 20.* That the common name of this color should be D&C Red No. 20, and the technical description should be "3-Ethoacetate of 9-o-carboxyphenyl-6-diethylamino-3-ethylimino-3-isoxanthene." The specification "Ether extracts, not more than 0.5 percent" should read "Ether extracts (from acid solution), not more than 0.5 percent." The specification "Sodium acetate, not more than 2.0 percent" is necessary and practicable in good manufacturing practice. The remaining specifications have all been found to be appropriate for other colors and are found to be appropriate for this color. The said color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

67

(Dibromofluorescein) *D&C Orange No. 5.* That the common name of this color should be D&C Orange No. 5. The technical description should be "4, 5-Dibromo-3, 6-fluorandiol." With respect to the specification for "Free bromine, not more than 0.02 percent," it is found that the amount present should be limited to not exceeding 0.02 percent. With regard to the specification "Permitted range of organically combined bromine in pure dye, 31.0-35.0 percent," this specification for all practical purposes is identical with the specification dealing with organically combined iodine previously referred to in the findings of fact in connection with the color FD&C Red No. 3. The proposed specification together with all the remaining specifications all of which have been previously approved for other colors, are hereby found to be appropriate for this color, and the said color with its specifications as set up in said exhibit is found to be harmless and suitable for use in drugs and cosmetics.

68

(Dibromofluorescein NA) *D&C Orange No. 6.* That the common name of this color should be D&C Orange No. 6, and the technical description should be "Disodium salt of 4, 5-dibromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." All of the specifications for this color have previously been approved for other colors and are found to be appropriate for this color. This color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

69

(Dibromofluorescein K) *D&C Orange No. 7.* That the common name of this color should be D&C Orange No. 7, and the technical description should be "Dipotassium salt of 4, 5-dibromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." Its specifications have been heretofore found to be appropriate in connection with other colors. This color with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

70

(Dichlorofluorescein) *D&C Orange No. 8.* That the common name of this color should be D&C Orange No. 8, and the technical description should be "4, 5-Dichloro-3, 6-fluorandiol." The specification for said color of "Free chlorine, not more than 0.02 percent" has not been referred to in these findings with respect to any other color. The proposed tolerance is comparable to a previous tolerance dealing with "free bromine." With respect to the specification "Permitted range of organically combined chlorine in pure dye, 16.0-19.0 percent," the requirement imposed by this specification would be for all practical purposes comparable to the requirement proposed for the color FD&C Red No. 3 which dealt with permitted range of organically com-

bined iodine in pure dye. The remaining specifications are already found to be appropriate and practicable in good manufacturing practice. This color is found to be harmless and suitable for use in drugs and cosmetics.

71

(Dichlorofluorescein NA) *D&C Orange No. 9.* That the common name of this color should be *D&C Orange No. 9*, and the technical description should be "Disodium salt of 9-o-carboxyphenyl-4, 5-dichloro - 6 - hydroxy - 3 - isoxanthone." The specifications for said color render it harmless and suitable for use in drugs and cosmetics.

72

(Diiodofluorescein) *D&C Orange No. 10.* That the common name of this color should be *D&C Orange No. 10*, and the technical description should be "4, 5-Diido-3, 6-fluorandiol." That the specification for said color of "Free iodine, not more than 0.05 percent" has not been referred to in connection with any previously mentioned color. The tolerance above referred to is practicable in good manufacturing practice. The remaining specifications are found to be appropriate. This color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

73

(Erythrosine Yellowish NA) *D&C Orange No. 11.* That the common name of this color should be *D&C Orange No. 11*, and the technical description should be "Disodium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5-diido-3-isoxanthone." The said color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

74

(Erythrosine Yellowish K) *D&C Orange No. 12.* That the common name of the color should be *D&C Orange No. 12*, and the technical description should be "Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5-diido-3-isoxanthone." This color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

75

(Erythrosine Yellowish NH) *D&C Orange No. 13.* That the common name of this color should be *D&C Orange No. 13*, and the technical description should be "Diammonium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5-diido-3-isoxanthone." This color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

76

(Tetrabromofluorescein) *D&C Red No. 21.* That the common name of this color should be "*D&C Red No. 21*." The technical description should read "2, 4, 5, 7-Tetrabromo-3, 6-fluorandiol." The

tolerance for volatile matter should be 6.0 percent. The specification dealing with pure dye should be "Pure dye (as determined gravimetrically), not less than 93.0 percent." The color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

77

(Eosin YS) *D&C Red No. 22.* That the common name of this color should be "*D&C Red No. 22*," and the technical description should read "Disodium salt of 2, 4, 5, 7-tetrabromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." This color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

78

(Eosin YSK) *D&C Red No. 23.* That the common name of this color should be "*D&C Red No. 23*." The technical description should be "Dipotassium salt of 2, 4, 5, 7-tetrabromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone." This color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

79

(Tetrachlorofluorescein) *D&C Red No. 24.* That the common name of this color should be "*D&C Red No. 24*," and the technical description should be "2, 4, 5, 7-Tetrachloro-3, 6-fluorandiol." The color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

80

(Tetrachlorofluorescein NA) *D&C Red No. 25.* That the common name of this color should be "*D&C Red No. 25*," and the technical description should be "Disodium salt of 9-o-carboxyphenyl-2, 4, 5, 7-tetrachloro-6-hydroxy-3-isoxanthone." The color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

81

(Tetrachlorofluorescein K) *D&C Red No. 26.* That the common name of this color should be "*D&C Red No. 26*," and the technical description should be "Dipotassium salt of 9-o-carboxyphenyl-2, 4, 5, 7-tetrachloro-6-hydroxy-3-isoxanthone." This color, with its specifications, is found to be harmless and suitable for use in drugs and cosmetics.

82

(Tetrachlorotetrabromofluorescein) *D&C Red No. 27.* That the common name of this color should be "*D&C Red No. 27*," and the technical description should be "2, 4, 5, 7-Tetrabromo-12, 13, 14, 15-tetrachloro-3, 6-fluorandiol." The specification for this color of "Free halogens, not more than 0.02 percent," has not been referred to in any findings with respect to any other color. The tol-

erance is practicable in good manufacturing practice. The specification "Permitted range of organically combined bromine in pure dye should read 38.5-42.5 percent." All the remaining specifications are found to be appropriate; and the said color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

83

(Phloxine B) *D&C Red No. 28.* That the common name of this color should be "*D&C Red No. 28*," and the technical description should read "Disodium salt of 2, 4, 5, 7-tetrabromo-9-(3, 4, 5, 6-tetrachloro-o-carboxyphenyl)-6-hydroxy-3-isoxanthone." This color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

84

(Orange TR) *D&C Orange No. 14.* That the common name of this color should be "*D&C Orange No. 14*," and the technical description should read "4, 5, 15-Tribromo-2, 7-dicarboxy-3, 6-fluorandiol." One specification for this color has not been referred to under any other finding with respect to any other color, namely, "Soluble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0%." If good manufacturing practice is followed, this specification is practicable. The color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

85

(Bluish Orange TR) *D&C Red No. 29.* That the common name of this color should be "*D&C Red No. 29*," and the technical description should be "1, 4, 5, 8, 15-Pentabromo-2,7-dicarboxy-3,6-fluorandiol." The color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

86

(Alizarin) *D&C Orange No. 15.* That the common name of this color should be "*D&C Orange No. 15*," and the technical description should be "1,2-Anthraquinonediol." The specification reading "Ether extracts, not more than 1.0 percent" should be "Ether insoluble matter, not more than 1.0%." This color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

87

(Helindone Pink CN) *D&C Red No. 30.* That the common name of this color should be "*D&C Red No. 30*," and the technical description should be "5,5'-Dichloro-3,3'-dimethylthioindigo." The specification "Matter, insoluble in xylene, not more than 1.0 percent" is one that has not been referred to in any of the findings with respect to any other color. Said tolerance is practicable in good manufacturing practice. The specification for "pure dye" should be "Pure dye

(as determined by titration with titanium trichloride), not less than 90.0%." The color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

88

(Orange G) *D&C Orange No. 3.* That the common name of this color should be "D&C Orange No. 3," and the technical description should be "Disodium salt of 1-phenylazo-2-naphthol-6,8-disulfonic acid." This color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

89

(Orange II) *D&C Orange No. 4.* That the common name of this color should be "D&C Orange No. 4," and the technical description should be "Monosodium salt of 1-p-sulfophenylazo-2-naphthol." The color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

90

(Resorcin Brown) *D&C Brown No. 1.* That the common name of this color should be "D&C Brown No. 1," and the technical description should read "Monosodium salt of 4-p-sulfophenylazo-2-(2, 4-xylylazo)-1, 3-resorcinol." The specification "m-Xylydine, not more than 0.2% is practicable in good manufacturing practice. This color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

91

(Alizurol Purple SS) *D&C Blue No. 3.* That the common name of this color should be "D&C Blue No. 3," and the technical description should read "1-Hydroxy-4 - p - toluiro-anthraquinone." The specification "p-Toluidine, not more than 0.2 percent," is practicable in good manufacturing practice. This color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

92

(Alphazurine FG) *D&C Blue No. 4.* That the common name of this color should be "D&C Blue No. 4," and the technical description should be "Diammonium Salt of 4-[(4-(N-ethyl-p-sulfobenzylamino)-phenyl)-(2 - sulfonphenyl)-methylene]-[1-(N-ethyl - N-p-sulfobenzyl) -  $\Delta^2$  - cyclohexadieniminol]." The color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

93

(Alizarin Astrol B) *D&C Blue No. 5.* That the common name of this color should be "D&C Blue No. 5," and the technical description should read "Monosodium salt of 1-methylamino-4-(o-sulfo - p - toluiro) - anthraquinone." This color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

94

(Indigo (Synthetic)) *D&C Blue No. 6.* That the common name of this color should be "D&C Blue No. 6," and the technical name should be "Indigotin." It is found that "Sulfated ash, not more than 2.0%" should be included in the specifications for this color. The specification "Matter, insoluble in dichlorhydrin, not more than 1.0 percent" has not been referred to in any finding with respect to any color. This specification is practicable in good manufacturing practice. The color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

95

(Naphthol Blue Black) *D&C Black No. 1.* That the common name of this color should be "D&C Black No. 1," and the technical name should read "Disodium salt of 8-amino-7-p-nitrophenylazo-2-phenylazo-1-naphthol-3,6-disulfonic acid." The specification "p-Nitroaniline, not more than 0.2 percent" is practicable in good manufacturing practice. The color, with its specifications is found to be harmless and suitable for use in drugs and cosmetics.

96

*Composite specifications for lakes each group — Names and designations for lakes—D&C.* That the findings of fact 26 makes it necessary to consolidate all Lakes into two groups under master specifications, one group to contain Lakes which are found to be harmless and suitable for use in drugs and cosmetics, and the other group to contain Lakes which are found to be harmless and suitable for use only in externally applied drugs and cosmetics. That such Lakes so consolidated should conform to the general specifications for straight colors as listed in Section 135.02 of the regulations hereby promulgated as well as to the master specification governing the particular group to which such Lakes belong. That such Lakes may be made from the following: (1) any straight color listed in Sections 135.03 and 135.04 of the regulations hereby promulgated (formerly Section 35.02 (a) and (b)), or (2) the aluminum salt prepared from FD&C Green No. 1, FD&C Green No. 2, FD&C Green No. 3, FD&C Yellow No. 1, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 1, FD&C Red No. 2, FD&C Red No. 3, FD&C Orange No. 1, D&C Red No. 5, D&C Red No. 6, D&C Red No. 10, D&C Red No. 19, D&C Red No. 20, D&C Orange No. 8, D&C Orange No. 10, D&C Red No. 21, D&C Orange No. 4, D&C Blue No. 4, D&C Blue No. 6; the barium salt prepared from FD&C Green No. 1, FD&C Green No. 2, FD&C Green No. 3, FD&C Yellow No. 1, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 1, FD&C Red No. 2, FD&C Orange No. 1, FD&C Blue No. 2, D&C Yellow No. 10, D&C Red No. 5, D&C Red No. 8, D&C Red No. 10, D&C Red No. 14, D&C Orange No. 4, D&C Blue No. 4; the zirconium salt prepared from

FD&C Yellow No. 5; the calcium salt prepared from FD&C Red No. 2, D&C Red No. 5, D&C Red No. 6, D&C Red No. 14, D&C Orange No. 15; the calcium salt of D&C Red No. 31 (which is the calcium salt of 3-hydroxy-phenylazo-2-naphthoic acid) extended on alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc or aluminum benzoate, and shall be considered to be individually listed for the purpose of this paragraph.

The name under which each lake shall be considered to be listed herein shall be formed as follows: (1) In the case of a straight color listed in Section 135.03 or 135.04 of the regulations hereby promulgated, the name under which such straight color is listed (except that in the case of colors listed in Section 135.03, the symbol "FD&C" shall be replaced by the symbol "D&C"), or, in the case of a color, the salt of which is included in clause 2 of this paragraph, the name of the color from which the salt is formed (except that in the case of colors designated by the symbol "FD&C" this symbol shall be replaced by the symbol "D&C"); (2) the name of the metallic base chemically combined in the color; and (3) the word "lake" (for example, the name of a lake prepared from the color "D&C Red No. 9" extended upon a substratum would be "D&C Red No. 9-Barium Lake," and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum would be "D&C Green No. 1-Aluminum Lake").

"Specifications:" Ether extracts, not more than 0.5 percent, soluble chlorides and sulfates (as sodium salts) not more than 5.0 percent, intermediates not more than 0.2 percent.

97

*Sections 135.03, 135.04 and 135.05—Prerequisites to certification.* That in Sections 135.03, 135.04 and 135.05 of the regulations hereby promulgated (formerly Section 35.02 (a), (b) and (c)) the following language should appear: "A batch of a straight color listed herein may be certified in accordance with the provisions of these regulations for use in \_\_\_\_\_, if such batch conforms to the requirements of Section 135.02 and to the specifications herein set forth for such color."

The blank should be filled in as follows:

In Section 135.03: "foods, drugs, and cosmetics"

In Section 135.04: "drugs and cosmetics," and

In Section 135.05: "externally applied drugs and cosmetics".

98

(Metanil Yellow) *Ext D&C Yellow No. 1.* That the common name of this color should be "Ext D&C Yellow No. 1," and the technical description should be "Monosodium salt of 4-m-sulfophenylazo-diphenylamine." The specification "Chloroform soluble matter, not more than 0.5 percent" has not been referred

to in any previous finding. This specification is practicable in good manufacturing practice. Another specification not referred to with respect to any color is "Diphenylamine, not more than 0.2 percent." This specification is practicable in good manufacturing practice. This color with its specifications is found to be harmless and suitable for use in externally applied drugs and cosmetics.

99

(Metanil Yellow CA) *Ext D&C Yellow No. 2.* That the common name of this color should be "Ext D&C Yellow No. 2," and the technical description should be "Calcium salt of 4-m-sulfophenylazo-diphenylamine." Its specifications are all found to be appropriate and practicable in good manufacturing practice, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

100

(Fast Light Yellow) *Ext D&C Yellow No. 3.* That the common name of this color should be "Ext D&C Yellow No. 3," and the technical description should be "Monosodium salt of 5-hydroxy-3-methyl-4-phenylazo-1-p-sulfophenylpyrazole." Its specifications are all found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

101

(Polar Yellow 5 G) *Ext D&C Yellow No. 4.* That the common name of this color should be "Ext D&C Yellow No. 4," and the technical description should be "Monosodium salt of 1-(4-chloro-o-sulfo-phenyl)-5-hydroxy-3-methyl-4-[p-(p-tolylsulfonyloxy)-phenylazo]-pyrazole." The specification "p-Aminophenol, not more than 0.2 percent" has not been referred to in connection with any other color. It and the remaining specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

102

(Amidonaphthol Red 6B) *Ext D&C Red No. 1.* That the common name of this color should be "Ext D&C Red No. 1," and the technical description should be "Disodium salt of 8-acetamido-2-p-acetamido-phenylazo-1-naphthol-3,6-disulphonic acid." The specification "p-Amino acetanilid, not more than 0.2 percent" has not been referred to with respect to any other color. The above limit is practicable in good manufacturing practice. The remaining specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

103

(Pigment Scarlet NA) *Ext D&C Red No. 2.* That the common name of this

color should be "Ext D&C Red No. 2," and the technical description should be "Trisodium salt of 1-o-carboxyphenylazo-2-naphthol-3,6-disulfonic acid." Its specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

104

(Violamine R) *Ext D&C Red No. 3.* That the common name of this color should be "Ext D&C Red No. 3," and the technical description should be "Disodium salt of 9-o-carboxyphenyl-6-(4-sulfo-o-toluino)-3-o-tolylimino-3-isoxanthene." Its specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

105

(Dichlorotetraiodofluorescein) *Ext D&C Red No. 4.* That the common name of this color should be "Ext D&C Red No. 4," and the technical description should be "12, 15-dichloro-2, 4, 5, 7-tetraiodo-3, 6-fluorandiol." Its specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

106

(Rose Bengal TD) *Ext D&C Red No. 5.* That the common name of this color should be "Ext D&C Red No. 5," and the technical description should be "Disodium salt of 9-(3, 6-dichloro-o-carboxyphenyl)-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone." Its specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

107

(Rose Bengal TDK) *Ext D&C Red No. 6.* That the common name of this color should be "Ext D&C Red No. 6," and the technical description should be "Dipotassium salt of 9-(3, 6-dichloro-o-carboxyphenyl)-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone." Its specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

108

(Alizarin Carmine) *Ext D&C Red No. 7.* That the common name of this color should be "Ext D&C Red No. 7," and the technical description should be "Monosodium salt of 3, 4-dihydroxy-2-anthraquinonesulfonic acid." The specification "Free acid as H<sub>2</sub>SO<sub>4</sub>, not more than 0.01 percent" has not been referred to in any preceding finding of fact with respect to any other color. This tolerance is practicable. The remaining specifications are found to be practicable in good manufacturing practice, and said color is found to be harmless and suit-

able for use in externally applied drugs and cosmetics.

109

(Methylene Blue) *Ext D&C Blue No. 1.* That the common name of this color should be "Ext D&C Blue No. 1," and the technical description should be "3-methochloride of 9-dimethylamino-3-methylimino-3-isophenothiazine." The specification "Dimethyl aniline, not more than 0.2 percent," not referred to in connection with any other color, is practicable in good manufacturing practice. The remaining specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

110

(Methylene Blue-Zinc Double Chloride) *Ext D&C Blue No. 2.* That the common name of this color should be "Ext D&C Blue No. 2," and the technical description should be "Zinc chloride double salt of 3-methochloride of 9-dimethylamino-3-methylimino-3-isophenothiazine." The specification "Zinc chloride (not a part of the dye), not more than 1.0 percent" has not been referred to with respect to any preceding color. The limit proposed is practicable in good manufacturing practice. The remaining specifications are found to be practicable, and said color is found to be harmless and suitable for use in externally applied drugs and cosmetics.

111

*Composite specifications for Lakes—Names and designations—Ext D&C.* That Lakes, which are harmless and suitable for use in externally applied drugs and cosmetics should be consolidated so as to have a master specification. That such Lakes so consolidated should conform to the general specifications for straight colors as listed in Section 135.02 of the regulations hereby promulgated as well as to the master specification governing the particular group to which such Lakes belong. That such Lakes may be made from the following:

(1) Any straight color listed in Section 135.05 of the regulations hereby promulgated, or

(2) The aluminum salt prepared from Ext D&C Yellow No. 1, Ext D&C Yellow No. 3;

The barium salt prepared from Ext D&C Yellow No. 3, Ext D&C Red No. 2;

The calcium salt prepared from Ext D&C Red No. 2, extended on alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, or aluminum benzoate, and shall be considered to be individually listed for the purpose of said section. The name under which each such lake shall be considered to be so listed shall be formed as follows:

First, in the case of a straight color listed in Section 135.05 the name under which such straight color is listed, or in the case of a color the salt of which is

included in clause (2) of this paragraph the name of the color from which the salt is formed;

Second, the name of the metallic base chemically combined in the color; and

Third, the word "lake."

The specifications for said lakes shall be as follows:

Ether extracts, not more than 0.5 percent; soluble chlorides and sulfates (as sodium salts), not more than 5.0 percent; intermediates, not more than 0.2 percent.

It is found that lakes made according to the preceding specifications are harmless and suitable for use in externally applied drugs and cosmetics.

112

*Mixtures which may be certified.* It is found that the matters and things set forth in Section 135.06 of the regulations hereby promulgated (formerly section 35.03), relating to mixtures which may be certified, are factually true and administratively desirable. It is found that a batch of a mixture which contains no straight color listed in Section 135.04, or 135.05 of such regulations (formerly Section 35.02 (b) or (c)), should be certified in accordance with the provisions relating to certification for use in foods, drugs, and cosmetics if each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture, and if each diluent in such batch of mixture is harmless and suitable for use therein, and if no diluent (except resins, natural gum, and pectin) in such mixture is a non-nutritive substance, unless such mixture is used for coloring a food specified in the request for certification of such batch submitted in accordance with Section 135.08 (c) of the regulations hereby promulgated (formerly Section 35.05 (c)), and such diluent in the usual process of manufacturing such food is removed and does not become a component of such food.

It is found that a batch of a mixture which contains no straight color listed in Section 135.05 of such regulations (formerly Section 35.02 (c)), or which contains a diluent not permitted by clause (3) of Section 135.06 of such regulations should be certified for use in drugs and cosmetics if each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and the color is not changed in composition, except such change as may be caused by the mixing and that it should also be required that each diluent in the batch is harmless and suitable for use therein.

It is also found that mixtures of coal-tar colors which are listed in Section 135.05 of such regulations (formerly Section 35.02 (c)), should be certified for use in externally applied drugs and cosmetics, if each coal-tar color used as an

ingredient in mixing such batch is from a previously certified batch and if the color previously certified has not changed in composition in any manner whatsoever since such previous certification, except by mixing into such batch of mixture. It should also be required that each diluent in such batch of mixture should be harmless and suitable for use therein.

113

*Sampling, storage, and packaging.* It is found that the matters and things set forth in Section 135.07 of the regulations hereby promulgated (formerly Section 35.04), are factually correct and administratively necessary. It is found that the administrative procedure to be followed in the sampling, storage, and packaging of coal-tar colors for certification is that samples be submitted by a person who seeks certification of a batch of coal-tar color, which sample should be taken from the batch sought to be certified after the batch has been so thoroughly mixed as to be of uniform composition throughout. It is found that to preserve the integrity of the sample immediately after it is taken it should be so packaged as to prevent changes in composition and the package containing the sample should be labeled in a conspicuous manner so as to show the name and post office address of the person who submitted the request, the name of such color, the batch number, and the quantity of such batch. Immediately after the sample is taken, the batch should be stored in containers which will prevent changes in the composition of the color, or the batch should be closed in packages for shipment or delivery and held in such condition until the batch either is certified or certification thereof is refused. If the batch is certified and at the time of the certification the batch or any part of it is stored, the storage should be maintained until the batch is either closed in packages for shipment in such a way as to prevent changes in composition, or is used by the person, who obtained the certificate, as an ingredient in a batch of a mixture on which such person submits a request for certification, or until the batch is used by the person who requested certification in coloring a food, drug, or cosmetic, in accordance with the restricted uses for which the batch was certified. That packages in which coal-tar colors are enclosed for shipment or delivery should be of such kind as to prevent changes in composition of the color and should be so closed or sealed that the package cannot be opened without destroying its seal. It is found that unavoidable changes in the moisture content of a coal-tar color which occur even through good commercial practice in storing, packing, and distributing the color should not be considered to be a change in its composition.

114

*Requests for certification.* It is found that Section 135.08 of the regulations hereby promulgated (formerly Section

35.05) is factually accurate and administratively necessary. When an application for certification is received from a foreign manufacturer, the application should be signed jointly by the manufacturer and his agent in the United States. A person who requests certification of a batch of a straight color should be required to submit as a part of the request, first, a statement showing whether or not he manufactured the batch, and if he did not, the name and post office address of the manufacturer, and, second, the name of such straight color as listed in the regulations hereby promulgated, the batch number and the quantity of such batch. It is found that a sample of one-half pound of such straight color is necessary for analysis, that the sample should be accurately representative of the batch from which it is taken, and that the fee for the certification of such batch should accompany the request. It is further found that any additional information or samples which the Food and Drug Administration may require to determine whether or not the batch complies with the requirements for the issuance of a certificate, should be made available upon the request of said administration. A person who applies for the certification of a batch of a mixture containing coal-tar color should submit a statement showing that he mixed such batch, the name of such mixture, the batch number, and the quantity of such batch. At the same time that a person requests certification of a batch of a mixture, he should submit information to the Food and Drug Administration showing lot numbers of the certified colors that were used and the amounts used, and that such colors have not changed in composition since certification, except such change as was incident to mixing into the batch. The name, quantity and quality of each diluent used in the preparation of a mixture should be stated by the person who applies for certification of a mixture. In the event the mixture contains non-nutritive substances (other than resins, natural gum, and pectin) which are permitted in coal-tar colors used for coloring foods only if the non-nutritive substance does not become a component of the food, the name of the food in which such color is to be used should be specified. A person who submits a request for certification of a mixture must affirmatively assure the Food and Drug Administration that the batch of color from which the sample was taken has been effectively mixed and should fully describe the process of mixing and make special reference to the precautions taken to render the batch uniform. A one-fourth pound sample is found to be sufficient for analysis, and such a sample should be submitted together with tender of payment of whatever fee is required. Such further samples and information as the Food and Drug Administration may require for the purpose of determining whether or not such mixed batch complies with the

specifications and regulations should be required to be submitted. A person who requests certification of a batch made by repacking a coal-tar color from a batch previously certified should submit as a part of his request, first, statements to the effect that he made the batch on which he requests certification by repacking such color, and that such color has not changed in composition in any manner whatever since such previous certification; second, the person who requests certification of a batch made by repacking a coal-tar color from a batch previously certified should submit as a part of his request information showing the name, quantity, and lot number of the repacked color, the batch number and quantity of such repacked batch; that he should also submit a sample consisting of one-fourth pound, accurately representative of the batch, and that the fee prescribed should accompany the request. Additional samples and additional information should be made available to the Food and Drug Administration upon request.

115

**Certification.** It is found that Section 135.09 of the regulations hereby promulgated (formerly Section 35.06) is factually correct and administratively necessary. That the Food and Drug Administration should issue a certificate to the person who submits a request for certification of straight coal-tar colors and mixtures of coal-tar colors, if after such investigation as the Food and Drug Administration determines to be necessary, it is found that the request appears to contain no untrue statement of any material fact. That in the case of a straight color it conforms to the specifications set forth herein, and in the case of a mixture containing a diluent, the diluent is harmless and suitable for use therein, and that the batch covered by such request otherwise appears to comply with the regulations hereby promulgated. It is found that the certificates to be issued by the Food and Drug Administration should show the lot number assigned to the batch, the percentage of pure dye as determined by analysis, and that such batch, subject to the terms, conditions and restrictions prescribed hereinafter, should thus become a certified batch for use in food, drugs, and cosmetics, or for use only in drugs and cosmetics, or for use only in externally applied drugs and cosmetics, as the case may be. It is further found that if the Food and Drug Administration finds after such reasonable investigation as may be considered necessary that a request for certification of a batch of coal-tar color dealt with in such request does not comply with the requirements to which reference has been made for the issuance of a certificate, the Food and Drug Administration should refuse to certify such batch and they should give notice to the person who

submitted the request stating the reasons for refusing to issue a certificate.

116

**Limitations of certificates.** It is found that the matters and things set forth in Section 135.10 of the regulations hereby promulgated (formerly Section 35.07), are factually true and administratively necessary. If a certificate is issued upon a misrepresentation of a material fact, such certificate should not be effective, and the color should be considered to be from a batch that has not been certified. If between the time a sample from a batch of coal-tar color is submitted with a request for certification and the time the certificate is issued the batch changes in composition, the certificate should not be effective and the color from such batch should be considered to be from a batch that has not been certified. If at any time after a certificate is received by the person to whom it is issued any color from the batch covered by the certificate becomes changed in composition in any manner, the certificate should expire with respect to such changed color and the color should thenceforth be considered as from a batch that has not been certified, except that if the only change in the color is incident to the use of the batch, or a portion of it, in preparing a batch of a mixture for certification as a mixture, the change in composition of the color resulting from such mixing should not cause the color to become an uncertified color. Any certificate that may be issued should expire if the package in which the certified color is closed for shipment or delivery is opened, except when such opening is solely for the purpose of repacking by the person to whom the certificate was issued; and after such expiration such color should be considered to be from a batch which has not been certified. An exception, however, should be made when colors certified for foods, drugs, and cosmetics, are used in coloring foods, drugs, and cosmetics, when coal-tar colors certified for use in drugs and cosmetics are used in coloring drugs and cosmetics, and when coal-tar colors certified for use in externally applied drugs and cosmetics are used for these restricted purposes. The lot should also not be considered an uncertified color if the package is opened for the sole purpose of certifying a batch made by repacking such color, or for the purpose of certifying a batch of a mixture in which the previously certified color is used as an ingredient. A certificate should not be effective with respect to a package of coal-tar color and such color should be considered to be from a batch that has not been certified if such package is shipped or delivered under a label which does not comply in all respects with the requirements concerning labeling hereinafter set forth. If a mixture from a batch containing a non-nutritive diluent is certified only for use in a particular food because the

diluent does not become a part of such food and such mixture is in fact used in coloring some other food, the mixture should be considered to be from a batch that has not been certified. If a coal-tar color is certified for any restricted use and is used in foods, drugs, or cosmetics, in any way other than that as contemplated in the restrictions imposed, such coal-tar color should be considered to be from a batch that has not been certified.

117

**Labeling.** That the matters and things set forth in Section 135.11 of the regulations hereby promulgated (formerly Section 35.08), are factually correct and administratively necessary. It is found that the label of each package of coal-tar color from a batch that has been certified should bear all words, statements and information required by, or under authority of the Food, Drug, and Cosmetic Act of 1938, as well as the name of such color; the lot number assigned to such batch by the Food and Drug Administration at the time such batch was certified; the percentage of pure dye which is found by chemical analysis by the Food and Drug Administration to be present in such color; and in the case of coal-tar colors, certified for use in drugs and cosmetics, the statement "Not for use in coloring foods"; and that those certified for use in externally applied drugs and cosmetics, should bear the label statement "Not for use in coloring food, or in coloring any drug or cosmetic used internally, or on the lips or any mucous membrane". If a batch of such color is a mixture containing a nonnutritive ingredient permitted only because such nonnutritive ingredient does not become a component of the food colored by such mixture, the label should bear the statement "Not for use in coloring any food except \_\_\_\_\_," (the blank to be filled in by the name of such food). The percentage of pure dye in a coal-tar color should be stated upon the label and should be the minimum percentage by weight. The percentage of pure dye, for the purposes of the declaration upon the label should be the percentage of pure dye stated in the certificate for such color issued by the Food and Drug Administration. It is found that the label of a certified straight color should state the name by which such color is listed in the regulations hereby promulgated. It is further found that no batch of a mixture should be certified if the name of such mixture is false or misleading in any particular, or the name of the mixture is the same as or simulates the name of a previously certified batch of a mixture containing a different substance, or a different percentage of a pure dye, but that this requirement should not apply if the person who requests the certification of such batch is the owner of such name and has given three months' written notice to the Food and Drug Ad-

ministration, specifying the change to be made in the composition of the mixture.

118

*Records of distribution.* That the matters and things set forth in Section 135.12 of the regulations hereby promulgated (formerly Section 35.09), are found to be factually correct and administratively necessary. It is found that the person to whom a certificate is issued should keep a complete record showing the disposition of all coal-tar color of the batch covered by the certificate; that he should make this information readily available upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States acting on behalf of the Secretary of Agriculture, at all reasonable hours until at least one year after disposal of all such color. That such officer or employee should also be given full opportunity to make inventories of stocks of such color on hand and otherwise to check the correctness and completeness of such records. Records required to be kept should consist of

(1) Records showing each quantity used by the person who obtained a certificate from the batch and the date and time of such use; and

(2) The date and quantity of each shipment or delivery from each such batch, and the name and post office address of the person to whom such shipment or delivery was made.

119

*Authority to refuse certification service.* That the matters and things set forth in Section 135.13 of the regulations hereby promulgated (formerly Section 35.10), are found to be factually correct and administratively necessary. It is found that the Secretary of Agriculture should suspend immediately further certification service to any person who obtained a certificate through fraud or misrepresentation of a material fact, or who falsified the records found to be essential to the maintenance of an effective certification system, or who fails to keep such records or to make them available to an officer or employee of the Food and Drug Administration or to any other officer or employee of the United States acting on behalf of the Secretary of Agriculture, or who fails fully to accord to such officials opportunities to make inventories of stocks on hand, or otherwise to check the correctness and completeness of such records as are necessary. Such suspension should continue unless and until such person shows adequate cause why the suspension should be terminated.

120

*Procedure for admitting colors to listing.* That the matters and things that appear in Section 135.14 of the regulations hereby promulgated (formerly Sec-

tion 35.11), are found to be factually correct and administratively necessary. Each application for the admission of any coal-tar color to listing, which said color has not previously been listed, should be accompanied by

(1) Full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in foods, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

(2) A full statement of the percentages and compositions of the pure dye and all intermediates and other impurities contained in such color;

(3) A full statement showing the identity, purity, and quantity, or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) A full description of practical and accurate methods of analysis for the quantitative determination of pure dye and all intermediates and other impurities contained in such color;

(5) A full description of practical and accurate methods for the identification of such dye in foods, drugs, and cosmetics, colored therewith, or in drugs and cosmetics colored therewith;

(6) A five-pound sample of such color (unless the Food and Drug Administration authorizes or requires submission of other quantity suitable to the need for investigation) taken from a batch produced under practical manufacturing conditions, and accurately representative of such batch; and

(7) Whatever advance deposit is required in the regulations. It is found that if the Secretary of Agriculture should determine after such investigation as he considers to be necessary that

(1) Such color is harmless and suitable for use in foods, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics;

(2) Practical and accurate methods of analysis exist for the quantitative determination of the pure dye and all intermediates and other impurities contained in such color; and

(3) Practical and accurate methods exist for the identification of such dye in foods, drugs, and cosmetics, colored therewith, or in drugs and cosmetics colored therewith; that when information as above specified is submitted, the Secretary of Agriculture should, for the purpose of listing such color, proceed in the manner required for a proposed amendment to the regulations as set up in Section 701 (e) of the Federal Food, Drug, and Cosmetic Act. It is further found that if the Secretary of Agriculture, after such investigation as he may consider necessary, determines that any color does not comply with the said requirements

with respect to the procedure for the listing of coal-tar colors for certification, the Secretary of Agriculture should give notice thereof to the applicant, stating the respects in which such color does not so comply.

121

*Fees.* That the matters and things set forth in Section 135.15 of the regulations hereby promulgated (formerly Section 35.12), are found to be factually correct and administratively necessary. It is found that the fee for the certification of a batch of straight color should be \$15; that the fee for the certification of a batch of a mixture, or of a repacked batch of a previously certified coal-tar color, should be \$8. An application for the listing of a coal-tar color should be accompanied by an advance deposit of \$500 to cover the cost incurred by the Department in making such investigations as it may consider necessary to act upon the application. Subsequent advance deposits of the same amount or of different amounts should be made, if the Food and Drug Administration authorizes a deposit of another amount, or whenever necessary to prevent arrears in the payment of a fee. It is found that if any excess advance deposit is made, the same should be returned to the applicant after the close of the investigation which the Department may determine to be essential. It is further found that all fees and deposits required to be paid should be paid by money order, bank draft, or certified check, drawn to the order of the Treasurer of the United States, collectible at par at Washington, D. C., and that all earned fees should be deposited in the Treasury of the United States to the credit of Miscellaneous Receipts, Department of Agriculture.

122

*Colors may be certified for purposes indicated.* That all of the straight colors listed in the regulations hereby promulgated, including lakes, with the specifications therefor, have been examined and approved by chemists and pharmacologists of the Food and Drug Administration, United States Department of Agriculture, and have been found by said chemists and pharmacologists to be harmless and suitable for the uses described in such regulations; that the said colors so named and tested, and all of them, are hereby found to be harmless and suitable for such uses, namely: the colors listed in Section 135.03 of such regulations, in the identities established by the preceding findings of fact, are found to be harmless and suitable for use in foods, drugs, and cosmetics; the colors listed in Section 135.04 of such regulations, in the identities established by the preceding findings of fact, are found to be harmless and suitable for use in drugs and cosmetics; the colors in

the form of lakes, listed in such section, in the identities established by the preceding findings of fact, are found to be harmless and suitable for use in drugs and cosmetics; the colors listed in Section 135.05 of such regulations, in the identities established by the preceding findings of fact, are found to be harmless and suitable for use in externally applied drugs and cosmetics. The colors in the form of lakes, listed in such section, in the identities established by the preceding findings of fact, are found to be harmless and suitable for use in externally applied drugs and cosmetics; and such colors, including the said lakes, are found to be entitled to be listed under the sections just named in the regulations hereby promulgated providing for the listing of coal-tar colors which are harmless and suitable for use in foods, drugs, and cosmetics under the Federal Food, Drug, and Cosmetic Act in order that batches of said colors may be certified by the Secretary of Agriculture for the purposes aforesaid.

Based upon the foregoing findings of fact, conclusions in the form of regulations are hereby made and promulgated, as follows:

#### REGULATIONS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

##### REGULATIONS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT FOR THE LISTING OF COAL-TAR COLORS, CERTIFICATION OF BATCHES THEREOF, AND PAYMENT OF FEES FOR SUCH SERVICE

**§ 135.01 Definitions.** For the purposes of these regulations—

(a) The term "coal-tar color" means articles which (1) are composed of or contain any substance derived from coal-tar, or any substance so related in its chemical structure to a constituent of coal-tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, cosmetic, or the human body or any part thereof, are capable (alone or through reaction with other substance) of imparting color thereto.

(b) The term "straight color" means a coal-tar color listed in Section 135.03, 135.04, or 135.05, and includes such impurities and substrata as are contained in such color.

(c) The term "mixture" means a coal-tar color made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(d) The term "diluent" means any component of a coal-tar color, except a straight color.

(e) The term "pure dye" means the coal-tar dye contained in a coal-tar color, exclusive of any intermediate or other impurity, or of any diluent or substratum contained therein.

(f) The term "substratum" means the substance on which the pure dye in a lake is extended.

(g) The term "alumina" means a suspension in water of precipitated aluminum hydroxide.

(h) The term "blanc fixe" means a suspension in water of precipitated barium sulfate.

(i) The term "gloss white" means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term "mixed oxides" means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k) The term "batch" means a quantity of coal-tar color which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(l) The term "batch number" means the number assigned to a batch by the person who requests certification thereof.

(m) The term "lot number" means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(n) The term "externally applied drugs and cosmetics" means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o) The authorization contained in these regulations for the certification of coal-tar colors shall not be considered to authorize the certification of any coal-tar color for use in any article which is applied to the area of the eye. A coal-tar color used in any such article which is so applied shall be considered to be from a batch that has not been certified in accordance with these regulations, even though such color is from a batch that has been certified for other use.

(p) The term "area of the eye" means the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(q) The definitions and interpretations of terms contained in section 201 of the Act shall be applicable also to such terms when used in these regulations.

**§ 135.02 General specification for straight colors.** No batch of a straight color listed in section 135.03, 135.04, or 135.05 shall be certified under these regulations unless—

(a) It is free from all impurities (other than those named in paragraph (b) or in the specifications set forth in such section for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in section 135.03—

Lead (as Pb), not more than 0.001 percent.

Arsenic (as As<sub>2</sub>O<sub>3</sub>), not more than 0.00014 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in section 135.04 or 135.05—

Lead (as Pb), not more than 0.002 percent.

Arsenic (as As<sub>2</sub>O<sub>3</sub>), not more than 0.0002 percent.

Heavy metals (except Pb and As) by precipitation as sulfides, not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in section 135.04 or 135.05—soluble barium (in dilute HCl) (as BaCl<sub>2</sub>), not more than 0.05 percent.

**§ 135.03 List of straight colors and specifications for their certification for use in food, drugs, and cosmetics.** A batch of a straight color listed herein may be certified, in accordance with the provisions of these regulations, for use in food, drugs, and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specifications herein set forth for such color.

#### FD&C Green No. 1

##### Specifications

Monosodium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)-diphenylmethylenel-[1-(N-ethyl-N-p-sulfonumbenzyl)-Δ<sup>2</sup>-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### FD&C Green No. 2

##### Specifications

Disodium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)-phenyl]- (4-sulfonium-phenyl)-methylenel-[1-(N-ethyl - N-p-sulfobenzyl)-Δ<sup>2</sup>-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes (as FD&C Green No. 1), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

**FD&C Green No. 3**

## Specifications

Disodium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)- phenyl]-4-hydroxy-2-sulfoniumphenyl)- methylene] - [1-N-ethyl-(N-p-sulfobenzyl)-Δ2 5-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Yellow No. 1**

## Specifications

Disodium salt of 2, 4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Yellow No. 2**

## Specifications

Dipotassium salt of 2, 4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Yellow No. 3**

## Specifications

1-Phenylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 99° C.

**FD&C Yellow No. 4**

## Specifications

1-o-Tolylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 120° C.

**FD&C Yellow No. 5**

## Specifications

Trisodium salt of 3-carboxy-5-hydroxy-1-p-sulfophenyl-4-p-sulfophenyl-azo-pyrazole.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.3 percent.

Phenyldiazine-p-sulfonic acid, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidary dyes, not more than 3.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Yellow No. 6**

## Specifications

Disodium salt of 1-p-sulfophenylazo-2-naphthol-6-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Red No. 1**

## Specifications

Disodium salt of 1-pseudocumylazo-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

Pseudo-cumidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Lower sulfonated dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Boiling range of crude pseudo-cumidine, or of pseudo-cumidine obtained by reduction of the dye, 220-245° C.

**FD&C Red No. 2**

## Specifications

Trisodium salt of 1-(4-sulfo-1-naphthylazo)-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidary dyes, not more than 4.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Red No. 3**

## Specifications

Disodium salt of 9-o-carboxyphenyl-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 12.0 percent.

Water insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Sodium carbonate, not more than 0.5 percent.

Sodium iodide, not more than 0.4 percent.

Mixed oxides, not more than 1.0 percent.

Permitted range of organically combined iodine in pure dye, free from water of crystallization, 56.8 to 58.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

**FD&C Red No. 4**

## Specifications

Disodium salt of 2-(5-sulfo-2, 4-xylylazo)-1-naphthol-4-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

#### FD&C Orange No. 1

##### Specifications

Monosodium salt of 4-p-sulfophenyl-azo-1-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

alpha-Naphthol, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Mixed oxides, not more than 1.0 percent.

Orange II, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

#### FD&C Orange No. 2

##### Specifications

1-o-Tolylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

o-Toluidine, not more than 0.5 percent.

beta-Naphthol, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 98.0 percent.

Melting point, not less than 128.0° C.

#### FD&C Blue No. 1

##### Specifications

Disodium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl]-[2-sulfoniumphe nyl]-methylene)-[1-N-ethyl-N-p-sulfobenzyl]-Δ<sup>2,5</sup>-cyclohexadienimine]

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Sodium acetate, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### FD&C Blue No. 2

##### Specifications

Disodium salt of 5, 5'-indigotindisulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 7.0 percent.

Mixed oxides, not more than 1.0 percent.

Lower sulfonated dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**§ 135.04 List of straight colors and specifications for their certification for use in drugs and cosmetics.** (a) A batch of a straight color listed herein may be certified, in accordance with the provisions of these regulations, for use only in drugs and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specifications herein set forth for such color.

#### D&C Green No. 4

##### Specifications

Calcium salt of 4-([4-(N-ethyl-p-sulfobenzylamino)-phenyl]-[4-sulfoniumphe nyl]-methylene)-[1-(N-ethyl-N-p-sulfobenzyl)-Δ<sup>2,5</sup>-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Subsidiary dyes (as FD&C Green No. 1), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### D&C Green No. 5

##### Specifications

Disodium salt of 1, 4-bis(c-sulfo-p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

1, 4-Dihydroxy-anthraquinone, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 15.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 75.0 percent.

#### D&C Green No. 6

##### Specifications

1, 4-Bis (p-toluino)-anthraquinone. Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 1.5 percent.

Intermediates, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

Melting point, not less than 210° C.

#### D&C Yellow No. 7

##### Specifications

3, 6-Fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

#### D&C Yellow No. 8

##### Specifications

Disodium salt 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### D&C Yellow No. 9

##### Specifications

Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

**D&C Yellow No. 10**

## Specifications

Disodium salt of disulfonic acid of 2-(2-quinolyl)-1, 3-indandione.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Quinaldine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 82.0 percent.

**D&C Red No. 5**

## Specifications

Disodium salt of 1-xylylazo-2-naphthol-3, 6-disulfonic acid.

Volatile matter (at 135° C.), not more than 12.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Xylidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

**D&C Red No. 6**

## Specifications

Monosodium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

**D&C Red No. 7**

## Specifications

Calcium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 8.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates (as calcium salts), not more than 6.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**D&C Red No. 8**

## Specifications

Monosodium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Lake Red C Amine, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**D&C Red No. 9**

## Specifications

Barium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Lake Red C Amine, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 87.0 percent.

**D&C Red No. 10**

## Specifications

Monosodium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalene sulfonic acid.

Volatile matter (135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent. beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

**D&C Red No. 11**

## Specifications

Calcium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent. beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

**D&C Red No. 12**

## Specifications

Barium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent. beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

**D&C Red No. 13**

## Specifications

Strontium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent. beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfate (as sodium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

**D&C Red No. 14**

## Specifications

Monosodium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

**D&C Red No. 15**

## Specifications

Barium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

#### D&C Red No. 16

##### Specifications

Calcium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

#### D&C Red No. 17

##### Specifications

1-p-Phenylazophenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (in toluene), not more than 3.0 percent.

Aniline, not more than 0.2 percent.

Amino-azo-benzene, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

#### D&C Red No. 18

##### Specifications

1-Xylylazoxylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 2.0 percent.

Sulfated ash, not more than 2.0 percent.

Water soluble matter, not more than 0.5 percent.

Matter, insoluble in carbon tetrachloride, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 1.0 percent.

Amino-azo-xlyene, not more than 0.2 percent.

Xyldine, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

#### D&C Red No. 19

##### Specifications

3-Ethechloride of 9-o-carboxyphenyl-6 - diethylamino-3-ethylimino-2-isoxanthene.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts (from acid solution), not more than 0.5 percent.

Diethyl-m-aminophenol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 92.0 percent.

#### D&C Red No. 20

##### Specifications

3-Ethoacetate of 9-o-carboxyphenyl-6 - diethylamino - 3 - ethylimino - 3 - isoxanthene.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts (from acid solution), not more than 0.5 percent.

Diethyl-m-aminophenol, not more than 0.2 percent.

Sodium acetate, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 92.0 percent.

#### D&C Orange No. 5

##### Specifications

4, 5-Dibromo-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 31.0-35.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

#### D&C Orange No. 6

##### Specifications

Disodium salt of 4, 5-dibromo-9-o-carboxyphenyl - 6 - hydroxy - 3 - isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Orange No. 7

##### Specifications

Dipotassium salt of 4, 5-dibromo-9-o-carboxyphenyl - 6 - hydroxy - 3 - isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 26.0-30.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Orange No. 8

##### Specifications

4, 5-Dichloro-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 16.0-19.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

#### D&C Orange No. 9

##### Specifications

Disodium salt of 9-o-carboxyphenyl-4, 5-dichloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 14.5-17.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

#### D&C Orange No. 10

##### Specifications

4, 5-Diiodo-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 41.5-45.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Orange No. 11

##### Specifications

Disodium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 38.5-42.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Orange No. 12

##### Specifications

Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free Iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 36.5-40.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Orange No. 13

##### Specifications

Diammonium salt of 9-o-carboxyphenyl-6-hydroxy-4, 5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of ammonium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 39.0-43.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Red No. 21

##### Specifications

2, 4, 5, 7-Tetrabromo-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 47.5-51.5 percent.

Pure dye (as determined gravimetrically), not less than 93.0 percent.

#### D&C Red No. 22

##### Specifications

Disodium salt of 2, 4, 5, 7-tetrabromo-9-o-carboxy-phenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 44.5-48.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Red No. 23

##### Specifications

Dipotassium salt of 2, 4, 5, 7-tetrabromo-9-o-carboxy-phenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 15.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye (free from water or alcohol of crystallization), 42.0-46.0 percent.

Pure dye (as determined gravimetrically), not less than 80.0 percent.

#### D&C Red No. 24

##### Specifications

2, 4, 5, 7-Tetrachloro-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

#### D&C Red No. 25

##### Specifications

Disodium salt of 9-o-carboxyphenyl-2, 4, 5, 7-tetrachloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 26.0-29.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Red No. 26

##### Specifications

Dipotassium salt of 9-o-carboxyphenyl-2, 4, 5, 7-tetrachloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 24.5-27.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Red No. 27

##### Specifications

2, 4, 5, 7-tetrabromo-12, 13, 14, 15-tetrachloro-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 1.0 percent.

Permitted range of organically combined bromine in pure dye, 38.5-42.5 percent.

Permitted range of organically combined chlorine in pure dye, 16.0-19.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

#### D&C Red No. 28

##### Specifications

Disodium salt of 2, 4, 5, 7-tetrabromo-9-(3, 4, 5, 6-tetrachloro-o-carboxyphenyl)-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye 36.5-40.5 percent.

Permitted range of organically combined chlorine in pure dye, 16.0-18.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

#### D&C Orange No. 14

##### Specifications

4, 5, 15-Tribromo-2, 7-dicarboxy-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Insoluble matter (alkaline solution), not more than 0.3 percent.

Soluble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye 36.0-40.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

#### D&C Red No. 29

##### Specifications

1, 4, 5, 8, 15-Pentabromo-2, 7-dicarboxy-3, 6-fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Insoluble matter (alkaline solution), not more than 0.3 percent.

Soluble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 47.0-51.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

#### D&C Orange No. 15

##### Specifications

1, 2-Anthraquinonediol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Water soluble matter, not more than 1.5 percent.

Ether insoluble matter, not more than 1.0 percent.

Sodium chloride, not more than 1.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

Melting point, not less than 285° C.

#### D&C Red No. 30

##### Specifications

5, 5'-Dichloro-3, 3'-dimethyl-thioindigo.

Volatile matter (at 135° C.), not more than 5.0 percent.

Matter, insoluble in xylene, not more than 1.0 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

#### D&C Orange No. 3

##### Specifications

Disodium salt of 1-phenylazo-2-naphthol-6, 8-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### D&C Orange No. 4

##### Specifications

Monosodium salt of 1-p-sulfophenyl-azo-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

#### D&C Brown No. 1

##### Specifications

Monosodium salt of 4-p-sulfophenyl-azo-2-(2, 4-xylylazo)-1, 3-resorcinol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

m-Xylylidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### D&C Blue No. 3

##### Specifications

1-Hydroxy-4-p-toluene-anthraquinone.

Volatile matter (at 135° C.) not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in carbon tetrachloride, not more than 1.5 percent.

p-Toluidine, not more than 0.2 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 96.0 percent.

Melting point, not less than 185° C.

#### D&C Blue No. 4

##### Specifications

Diammonium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)-phenyl]-2-sulfo-

niumphenyl) - methylene) - [1 - (N-ethyl-N - p - sulfobenzyl) -  $\Delta^{\text{a},\text{b}}$  - cyclohexadienimine].

Volatile matter (at 135° C.) not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of ammonium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### D&C Blue No. 5

##### Specifications

Monosodium salt of 1-methyldiamino-4-(o-sulfo-p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined nitrogen or sulphur), not less than 80.0 percent.

#### D&C Blue No. 6

##### Specifications

##### Indigotin.

Volatile matter (at 135° C.), not more than 5.0 percent.

Sulfated ash, not more than 2.0 percent.

Matter, insoluble in dichlorhydrin, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride) not less than 95.0 percent.

#### D&C Black No. 1

##### Specifications

Disodium salt of 8-amino-7-p-nitrophenylazo-2-phenylazo-1-naphthol-3, 6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

p-Nitroaniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### Lakes

Any lake, made as hereinafter prescribed, of

(1) a straight color listed above in this subsection or in section 135.03; or

(2) the aluminum salt prepared from

FD&C Green No. 1, FD&C Green No. 2, FD&C Green No. 3, FD&C Yellow No. 1, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 1, FD&C Red No. 2, FD&C Red No. 3, FD&C Orange No. 1, D&C Red No. 5, D&C Red No. 6, D&C Red No. 10, D&C Red No. 19, D&C Red No. 20, D&C Red No. 21, D&C Orange No. 4, D&C Orange No. 8, D&C Orange No. 10, D&C Blue No. 4, D&C Blue No. 6; or

the barium salt prepared from

FD&C Green No. 1, FD&C Green No. 2, FD&C Green No. 3, FD&C Yellow No. 1, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 1, FD&C Red No. 2, FD&C Orange No. 1, FD&C Blue No. 2, D&C Yellow No. 10, D&C Red No. 5, D&C Red No. 8, D&C Red No. 10, D&C Red No. 14, D&C Orange No. 4, D&C Blue No. 4; or

the zirconium salt prepared from

FD&C Yellow No. 5; or

the calcium salt prepared from

FD&C Red No. 2, D&C Red No. 5, D&C Red No. 6, D&C Red No. 14, D&C Orange No. 15;

or the calcium salt prepared from D&C Red No. 31 (which is the calcium salt of 3-hydroxy-4-phenylazo-2-naphthoic acid). Such lake shall be made by the extension of one such straight color or one such salt on one or any combination of two or more of the following substrata: alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, or aluminum benzoate.

##### Specifications

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake under the designation "Lakes" in subsection (a) shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

First, in case the lake is made from a straight color listed in subsection (a) before "Lakes" or in section 135.03, the name under which such color is so listed; or in case the lake is made from a salt included in clause (2) under "Lakes" in subsection (a), the name of the color, as used in such clause, from which such salt is prepared; but in either case, if such name contains the symbol "FD&C," such symbol shall be replaced by the symbol "D&C."

Second, the name of the metallic base chemically combined in the color; and,

Third, the word "lake."

(For example, the name of a lake prepared from the color D&C Red No. 9 extended upon a substratum would be "D&C Red No. 9-Barium Lake," and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum would be "D&C Green No. 1-Aluminum Lake.")

§ 135.05 *List of straight colors and specifications for their certification for use in externally applied drugs and cosmetics.* (a) A batch of a straight color listed herein may be certified, in accordance with the provisions of these regulations, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specifications herein set forth for such color.

#### Ext D&C Yellow No. 1

##### Specifications

Monosodium salt of 4-m-sulfophenylazo-diphenylamine.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Chloroform soluble matter, not more than 0.5 percent.

Diphenylamine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 7.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

#### Ext D&C Yellow No. 2

##### Specifications

Calcium salt of 4-m-sulfophenylazo-diphenylamine.

Volatile matter (at 135° C.), not more than 10.0 percent.

Chloroform soluble matter, not more than 0.5 percent.

Diphenylamine, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

#### Ext D&C Yellow No. 3

##### Specifications

Monosodium salt of 5-hydroxy-3-methyl - 4 - phenylazo - 1-p-sulfophenylpyrazole.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.	Volatile matter (at 135° C.), not more than 10.0 percent.	Water insoluble matter, not more than 1.0 percent.
Mixed oxides, not more than 1.0 percent.	Water insoluble matter, not more than 1.0 percent.	Ether extracts, not more than 0.5 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.	Ether extracts, not more than 0.5 percent.	Chlorides and sulfates of potassium, not more than 5.0 percent.
<i>Ext D&amp;C Yellow No. 4</i>	<i>Ext D&amp;C Red No. 4</i>	Mixed oxides, not more than 1.0 percent.
Specifications	Specifications	Free halogens, not more than 0.02 percent.
Monosodium salt of 1-(4-chloro-o-sulophenyl)-5-hydroxy-3-methyl-4-[p-(p-tolylsulfonyloxy)-phenylazo]-pyrazole.	Chlorides and sulfates of sodium, not more than 10.0 percent.	Permitted range of organically combined iodine in pure dye, 50.0-54.0 percent.
Volatile matter (at 135° C.), not more than 5.0 percent.	Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.	Permitted range of organically combined chloride in pure dye, 6.5-8.0 percent.
Water insoluble matter, not more than 1.0 percent.	<i>Ext D&amp;C Red No. 4</i>	Pure dye (as determined gravimetrically), not less than 85.0 percent.
Ether extracts, not more than 0.5 percent.	Specifications	<i>Ext D&amp;C Red No. 7</i>
p-Aminophenol, not more than 0.2 percent.	12, 15-Dichloro-2, 4, 5, 7-tetraiodo-3, 6-fluorandiol.	Specifications
Chlorides and sulfates of sodium, not more than 10.0 percent.	Volatile matter (at 135° C.), not more than 5.0 percent.	Monosodium salt of 3,4-dihydroxy-2-anthraquinonesulfonic acid.
Mixed oxides, not more than 1.0 percent.	Insoluble matter (alkaline solution), not more than 1.0 percent.	Volatile matter (at 135° C.), not more than 10.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.	Ether extracts (from alkaline solution), not more than 0.5 percent.	Water insoluble matter, not more than 1.0 percent.
<i>Ext D&amp;C Red No. 1</i>	Sodium chloride, not more than 3.0 percent.	Chlorides and sulfates of sodium, not more than 6.0 percent.
Specifications	Mixed oxides, not more than 1.0 percent.	Mixed oxides, not more than 1.0 percent.
Disodium salt of 8-acetamido-2-p-acetamidophenylazo-1-naphthol-3, 6-disulfonic acid.	Free halogens, not more than 0.02 percent.	Free acid as H <sub>2</sub> SO <sub>4</sub> , not more than 0.01 percent.
Volatile matter (at 135° C.), not more than 10.0 percent.	Permitted range of organically combined iodine in pure dye, 54.0-58.0 percent.	Pure dye (by spectrophotometric determination), not less than 82.0 percent.
Water insoluble matter, not more than 1.0 percent.	Permitted range of organically combined chlorine in pure dye, 7.0-8.5 percent.	<i>Ext D&amp;C Blue No. 1</i>
Ether extracts, not more than 0.5 percent.	Pure dye (as determined gravimetrically), not less than 90.0 percent.	Specifications
p-Amino acetanilid, not more than 0.2 percent.	<i>Ext D&amp;C Red No. 5</i>	3-Methochloride of 9-dimethylamino-3-methylimino-3-isophenothenothiazine.
Chlorides and sulfates of sodium, not more than 6.0 percent.	Specifications	Volatile matter (at 110° C.), not more than 16.0 percent.
Mixed oxides, not more than 1.0 percent.	Disodium salt of 9-(3, 6-dichloro-o-carboxyphenyl)-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone.	Water insoluble matter, not more than 1.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.	Volatile matter (at 135° C.), not more than 10.0 percent.	Ether extracts, not more than 0.5 percent.
<i>Ext D&amp;C Red No. 2</i>	Water insoluble matter, not more than 1.0 percent.	Dimethyl aniline, not more than 0.2 percent.
Specifications	Ether extracts, not more than 0.5 percent.	Chlorides and sulfates of sodium, not more than 2.0 percent.
Trisodium salt of 1-o-carboxyphenylazo-2-naphthol-3, 6-disulfonic acid.	Chlorides and sulfates of sodium, not more than 5.0 percent.	Mixed oxides, not more than 1.0 percent.
Volatile matter (at 135° C.), not more than 10.0 percent.	Mixed oxides, not more than 1.0 percent.	Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.
Water insoluble matter, not more than 1.0 percent.	Free halogens, not more than 0.02 percent.	<i>Ext D&amp;C Blue No. 2</i>
Ether extracts, not more than 0.5 percent.	Permitted range of organically combined iodine in pure dye, 51.5-55.5 percent.	Specifications
Chlorides and sulfates of sodium, not more than 5.0 percent.	Permitted range of organically combined chlorine in pure dye, 6.8-8.3 percent.	Zinc chloride double salt of 3-methochloride of 9-dimethylamino-3-methylimino-3-isophenothenothiazine.
Mixed oxides, not more than 1.0 percent.	Pure dye (as determined gravimetrically), not less than 85.0 percent.	Volatile matter (at 110° C.), not more than 15.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.	<i>Ext D&amp;C Red No. 6</i>	Water insoluble matter, not more than 1.0 percent.
<i>Ext D&amp;C Red No. 3</i>	Specifications	Ether extracts, not more than 0.5 percent.
Specifications	Dipotassium salt of 9-(3, 6-dichloro-o-carboxyphenyl)-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone.	Dimethyl aniline, not more than 0.2 percent.
Disodium salt of 9-o-carboxyphenyl-6-(4-sulfo-o-toluino)-3-o-tolylimino-3-isoxanthene.	Volatile matter (at 135° C.), not more than 10.0 percent.	Chlorides and sulfates of sodium, not more than 2.0 percent.

Zinc chloride (not a part of the dye), not more than 1.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

#### Lakes

Any lake, made as hereinafter prescribed, of—

(1) a straight color listed above in this subsection; or

(2) the aluminum salt prepared from

EXT D&C Yellow No. 1

EXT D&C Yellow No. 3 or

the barium salt prepared from

EXT D&C Yellow No. 3

EXT D&C Red No. 2 or

the calcium salt prepared from

EXT D&C Red No. 2

Such lake shall be made by the extension of one such straight color or one such salt on one or any combination of two or more of the following substrata: alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, or aluminum benzoate.

#### Specifications

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake under the designation "Lakes" in subsection (a) shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

First, in case the lake is made from a straight color listed in subsection (a) before "Lakes", the name under which such color is so listed; or in case the lake is made from a salt included under clause (2) under "Lakes" in subsection (a), the name of the color, as used in such clause, from which such salt is prepared.

Second, the name of the metallic base chemically combined in the color; and,

Third, the word "lake."

(For example, the name of a lake prepared from the color Ext D&C Yellow No. 2 extended upon a substratum would be "Ext D&C Yellow No. 2—Calcium Lake", and a lake prepared by extending the barium salt prepared from Ext D&C Red No. 2 upon the substratum would be "Ext D&C Red No. 2—Barium Lake".)

**§ 135.06 Mixtures which may be certified.** (a) A batch of a mixture which contains no straight color listed in section 135.04 or 135.05 may be certified, in accordance with the provisions of these regulations, for use in food, drugs, and cosmetics, if—

(1) each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) no diluent (except resins, natural gum, and pectin) in such mixture is a non-nutritive substance, unless such mixture is for use in coloring a food specified in the request for certification of such batch submitted in accordance with section 135.08 (c), and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in section 135.05, or which contains a diluent not permitted by clause (3) of paragraph (a) of this section, may be certified, in accordance with the provisions of these regulations, for use only in drugs and cosmetics, if—

(1) each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture, and

(2) each diluent in such batch of mixture is harmless and suitable for use therein.

(c) A batch of a mixture which contains a straight color listed in section 135.05 may be certified, in accordance with the provisions of these regulations, for use only in externally applied drugs and cosmetics, if—

(1) each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture; and

(2) each diluent in such batch of mixture is harmless and suitable for use therein.

**§ 135.07 Sampling, storage, and packaging** (a) A sample of a coal-tar color which is to accompany a request for certification submitted in accordance with section 135.08 shall be taken from the batch covered by such request only after such batch has been so thoroughly mixed as to be of uniform composition throughout. Immediately after such sample is taken it shall be closed in a package of such kind as to prevent change in the composition of such sample. Such package shall be labeled to show conspicuously the name and post office address of the person submitting such request, the name of such color, and the batch number and quantity of such batch.

(b) Immediately after such sample is taken such batch shall be stored in containers of such kind as to prevent change in the composition of such color, or closed in packages for shipment or delivery, and so held until such batch is certified or certification thereof is refused. If such batch is certified and at the time of cer-

tification such batch or any part thereof is so stored, such storage shall be maintained until such batch or part is—

(1) closed in such packages,

(2) used by the person who obtained such certification as an ingredient in a batch of a mixture on which such person submits a request for certification in accordance with section 135.08, or

(3) used by such person in coloring a food, drug, or cosmetic, in accordance with the use for which such batch was certified.

(c) The package in which a coal-tar color is closed for shipment or delivery shall be of such kind as to prevent change in the composition of such color, and shall be so closed or sealed that such package cannot be opened without destroying such package or seal.

(d) For the purposes of these regulations an unavoidable change in the moisture content of a coal-tar color caused by ordinary and customary exposure that occurs in good storage, packing, and distribution practice, shall not be considered to be a change in the composition of such color.

#### § 135.08 Requests for certification.

(a) A request for certification of a batch of a coal-tar color shall be addressed to the Food and Drug Administration, U. S. Department of Agriculture, Washington, D. C. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) Except in the case of a request submitted under paragraph (d) of this section, a person who requests the certification of a batch of a straight color shall submit as part of his request statements showing—

(1) whether or not he manufactured such batch, and if he did not, the name and post office address of the manufacturer thereof; and

(2) the name of such color, as listed in section 135.03, 135.04, or 135.05, and the batch number and quantity of such batch.

(3) In the case of a lake, the process whereby such lake is made, including the name or names of the substrata present and the quantity thereof used for such batch. Such request shall be accompanied by a one-half pound sample taken from such batch and accurately representative thereof, and by payment of the fee prescribed by section 135.15 (a) (1). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such batch complies with the requirements laid down by section 135.09 (a) for the issuance of a certificate.

(c) Except in the case of a request submitted under paragraph (d) of this section, a person who requests certification of a batch of a mixture shall submit as part of his request statements—

(1) to the effect that he mixed such batch;

(2) showing the name of such mixture, and the batch number and quantity of such batch;

(3) showing the lot number of each coal-tar color used as an ingredient in mixing such batch, the quantity of such color so used, and that such color has not changed in composition in any manner whatever since certification, except by mixing into such batch;

(4) showing the name, quality, and quantity of each diluent used as an ingredient in mixing such batch;

(5) in case such mixture contains a diluent permitted by clause (3) of section 135.06 (a) only because such diluent does not become a component of a food colored by such mixture, specifying the name of such food; and

(6) describing fully the process of mixing, with special reference to the precautions taken to render such batch uniform in composition.

Such request shall be accompanied by a one-fourth pound sample taken from such mixed batch and accurately representative thereof, and by payment of the fee prescribed by section 135.15 (a) (2). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such mixed batch complies with the requirements laid down by section 135.09 (a) for the issuance of a certificate.

(d) A person who requests the certification of a batch made by repacking a coal-tar color from a batch previously certified under these regulations, shall submit as part of his request statements—

(1) to the effect that he made the batch on which he requests certification by repacking such color, and that such color has not changed in composition in any manner whatever since such previous certification; and

(2) showing the lot number of such previously certified batch, the name of such repacked color, and the batch number and quantity of such repacked batch. Such request shall be accompanied by a one-fourth pound sample taken from such repacked batch and accurately representative thereof, and by payment of the fee prescribed by section 135.15 (a) (2). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such repacked batch complies with the requirements of section 135.09 (a) for the issuance of a certificate.

**§ 135.09 Certification.** (a) If the Food and Drug Administration determines, after such investigation as it considers to be necessary, that—

(1) a request submitted in accordance with section 135.08 appears to contain no untrue statement of a material fact;

(2) in the case of a straight color, such color conforms to the specifications set forth therefor in sections 135.02, 135.03, 135.04, and 135.05;

(3) in the case of a mixture containing a diluent, such diluent is harmless and suitable for use therein; and

(4) the batch covered by such request otherwise appears to comply with these regulations, the Food and Drug Administration shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by section 135.10, is a certified batch for use in food, drugs, and cosmetics, or for use only in drugs and cosmetics, or for use only in externally applied drugs and cosmetics, as the case may be.

(b) If the Food and Drug Administration determines, after such investigation as it considers to be necessary, that a request submitted in accordance with section 135.08, or the batch of coal-tar color covered by such request, does not comply with the requirements laid down by paragraph (a) of this section for the issuance of a certificate, the Food and Drug Administration shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating its reasons for refusal.

**§ 135.10 Limitations of certificates.**

(a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and coal-tar color from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with these regulations.

(b) If, between the time a sample of coal-tar color accompanying a request for certification is taken and the time a certificate covering the batch of such color is received by the person to whom it is issued, any such color becomes changed in composition in any manner whatever, such certificate shall not be effective with respect to such changed color, and such changed color shall be considered to be from a batch that has not been certified in accordance with these regulations.

(c) If, at any time after a certificate is received by the person to whom it is issued, any color from the batch covered by such certificate becomes changed in composition in any manner whatever, such certificate shall expire with respect to such changed color. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with these regulations; except that such color shall not be so considered for the purpose of certifying a batch of a mixture in which such color was used as an ingredient, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any coal-tar color covered thereby if the package in which such color was closed for shipment or delivery

is opened, unless opened solely for repacking by the person to whom such certificate was issued. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with these regulations; except that such color shall not be so considered—

(1) when such color is used, subject to the restrictions prescribed by paragraphs (f), (g) and (h) of this section, in coloring a food, drug, or cosmetic;

(2) for the purpose of certifying a batch made by repacking such color; or

(3) for the purpose of certifying a batch of a mixture in which such color is used as an ingredient.

(e) A certificate shall not be effective with respect to a package of coal-tar color, and such color shall be considered to be from a batch that has not been certified in accordance with these regulations, if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by section 135.11 to appear thereon.

(f) If a mixture from a batch containing a diluent permitted by clause (3) of section 135.06 (a) only because such diluent does not become a component of a food colored by such mixture is used in coloring another food, such mixture so used shall be considered to be from a batch that has not been certified in accordance with these regulations.

(g) If coal-tar color from a batch which was certified for use in drugs and cosmetics only is used in coloring a food; such color so used shall be considered to be from a batch that has not been certified in accordance with these regulations.

(h) If a coal-tar color from a batch which was certified for use only in externally applied drugs and cosmetics is used in food or in other drugs or other cosmetics, such color so used shall be considered to be from a batch that has not been certified in accordance with these regulations.

**§ 135.11 Labeling.** (a) The label on each package of coal-tar color from a batch that has been certified in accordance with these regulations shall bear, in addition to other words, statements, and information required by or under authority of the Act to appear on such label—

(1) the name of such color;

(2) the lot number of such batch;

(3) the percentage of pure dye in such color; and,

(4) in case such batch was certified for use only in drugs and cosmetics, the statement "*Not for use in coloring food*"; or in case such batch was certified for use only in externally applied drugs and cosmetics, the statement "*Not for use in coloring food, or in coloring any drug or cosmetic used internally or on the lips or any mucous membrane*"; or in case such batch is a mixture containing a diluent permitted by clause (3) of section 135.06 (a) only because such diluent

does not become a component of a food colored by such mixture, the statement "Not for use in coloring any food except \_\_\_\_\_" (the blank to be filled in by the name of such food).

(b) The statement of the percentage of pure dye in a coal-tar color shall express the minimum percentage by weight and shall be the statement of the percentage of the pure dye stated in the certificate effective with respect to such batch of a coal-tar color.

(c) The name by which a straight color is designated on its label shall be the name by which such color is listed in section 135.03, 135.04, or 135.05.

(d) No batch of a mixture shall be certified under these regulations if—

(1) the name of such mixture is false or misleading in any particular; or

(2) the name of such mixture is the same as or simulates the name of a previously certified batch of a mixture containing a different substance, or a different percentage of a pure dye; but this provision shall not apply if the person who requests certification of such batch is the owner of such name and has given three months' written notice to the Food and Drug Administration specifying the change to be made in the composition of such mixture.

**§ 135.12 Records of distribution.** (a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the coal-tar color from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, such person, at all reasonable hours until at least one year after disposal of all such color, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show—

(1) each quantity used by such person from such batch and the date and kind of such use;

(2) the date and quantity of each shipment or delivery from such batch, and the name and post office address of the person to whom such shipment or delivery was made.

**§ 135.13 Authority to refuse certification service.** When it appears to the Secretary that a person has—

(1) obtained a certificate through fraud or misrepresentation of a material fact;

(2) falsified the records required to be kept by section 135.12; or

(3) failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the cor-

rectness of such records, as required by such section,

the Secretary may immediately suspend service to such person under these regulations, and may continue such suspension unless and until such person shows adequate cause why such suspension should be terminated.

**§ 135.14 Procedure for admitting colors to listing.** (a) An application for the admission of a coal-tar color to listing in section 135.03, 135.04, or 135.05 shall be accompanied by—

(1) full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

(2) a full statement of the percentages and compositions of the pure dye and all intermediates and other impurities contained in such color;

(3) a full statement showing the identity, purity, and quantity or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) a full description of practical and accurate methods of analysis for the quantitative determination of the pure dye and of all intermediates and other impurities contained in such color;

(5) a full description of practical and accurate methods for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith;

(6) a five-pound sample of such color (unless the Food and Drug Administration authorizes or requires submission of other quantity suitable to the need for investigation) taken from a batch produced under practical manufacturing conditions, and accurately representative of such batch; and

(7) the advance deposit prescribed by section 135.15 (b) (2).

(b) If the Secretary determines, after such investigation as he considers to be necessary, that—

(1) such color is harmless and suitable for use in foods, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics;

(2) practical and accurate methods of analysis exist for the quantitative determination of the pure dye and all intermediates and other impurities contained in such color; and

(3) practical and accurate methods exist for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith, the Secretary, for the purpose of listing such color in section 135.03, 135.04, or 135.05, shall proceed with a proposed amendment to these regulations as prescribed by section 701 (e) of the Act.

(c) If the Secretary, after such investigation as he considers to be necessary, determines that such color does not comply with the requirements laid down by paragraph (b) of this section with respect to procedure for the purpose of listing such color in section 135.03, 135.04, or 135.05, the Secretary shall give notice thereof to the applicant, stating the respects in which such color does not so comply.

**§ 135.15 Fees.** (a) (1) The fee for the service provided by these regulations, in the case of each request for certification submitted in accordance with section 135.08 (b), shall be \$15.

(2) The fee for the service provided by these regulations, in the case of each request for certification submitted in accordance with section 135.08 (c) or (d) shall be \$8.

(b) (1) The fee for the service provided by these regulations, in the case of each application for the admission of a coal-tar color to listing in section 135.03, 135.04, or 135.05, shall be the cost incurred by the Department in making the investigations contemplated by section 135.14 (b) and (c).

(2) Such application shall be accompanied by an advance deposit of \$500 to cover such fee, and thereafter advance deposits of the same amount (unless the Food and Drug Administration authorizes deposit in other amount) shall be made whenever necessary to prevent arrears in the payment of such fee. Any excess advance deposit so made shall be returned to the applicant after the close of such investigation;

(c) All fees required by these regulations should be paid by money-order, bank draft or certified check, drawn to the order of the Treasurer of the United States, collectible at par, at Washington, D. C.

(d) All earned fees shall be deposited in the Treasury of the United States to the credit of Miscellaneous Receipts, Department of Agriculture.

The Federal Food, Drug, and Cosmetic Act of June 25, 1938 (52 Stat. 1040; 21 U.S.C. 301 et seq.) becomes fully effective on June 25, 1939, on which date the repeal of The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., 1934 ed., Title 21, Secs. 1-15; 21 U.S.C., 1-15), becomes fully effective.

It is hereby found that emergency conditions now exist, within the meaning of Section 701 (e) (52 Stat. 1055; 21 U.S.C., 371 (e)), necessitating that the foregoing regulations become effective immediately, instead of ninety days from the promulgation thereof, in that, on the effective date of the Federal Food, Drug, and Cosmetic Act, namely June 25, 1939; (1) coal-tar colors may not generally be used in foods, drugs or cosmetics unless said colors are certified as harmless and suitable for such uses; (2) no coal-tar color whatsoever will be available for certification for use in foods, drugs or cosmetics unless such regulations become effective immedi-

ately; and (3) no method or system for the actual certification of such colors will be effective until thirty days, or more, thereafter, unless such regulations become effective immediately.

Wherefore, in view of the emergency conditions hereinbefore found to exist, and under and by virtue of Section 701 (e) (52 Stat. 1055; 21 U.S.C., 371 (e)) of the Federal Food, Drug, and Cosmetic Act, it is hereby ordered that the regulations hereby promulgated be and become effective upon the publication of this order in the Federal Register.

This the 4th day of May, 1939.

[SEAL] H. A. WALLACE,  
Secretary of Agriculture.

[F. R. Doc. 39-1533; Filed, May 5, 1939;  
1:04 p. m.]

## TITLE 6—AGRICULTURAL CREDIT FARM SECURITY ADMINISTRATION

[Administration Order 245]

EXERCISE OF RIGHTS, PRIVILEGES, OPTIONS,  
AND POWERS UNDER LEASES OF COMMERCIAL  
ENTERPRISES AT GREENBELT, GREENDALE  
AND GREENHILL PROJECTS

MAY 5, 1939.

I hereby delegate to the Administrator of the Farm Security Administration, United States Department of Agriculture, the authority vested in me to exercise, on behalf of the United States, all rights, privileges, benefits, options and powers conferred on the United States by and under the leases of the commercial enterprises at the Greenbelt, Greendale and Greenhills Projects of the Farm Security Administration. I hereby further delegate to the community managers of each of these projects the authority, with respect to the project under his jurisdiction, to approve in writing, on behalf of the United States, (1) the erection of all signs on the leased premises, and (2) any alteration or change in any of the leased premises.

Approved:

[SEAL] H. A. WALLACE,  
Secretary of Agriculture.

Recommended:

WILL W. ALEXANDER,  
Administrator.

[F. R. Doc. 39-1544; Filed, May 6, 1939;  
12:15 p. m.]

## TITLE 7—AGRICULTURE FEDERAL CROP INSURANCE CORPORATION

[F. C. I. R.—Series 1, No. 1, Sup. 5]

### PART 401—WHEAT CROP INSURANCE REGULATIONS AMENDMENTS

By virtue of the authority vested in the Federal Crop Insurance Corporation

by the Federal Crop Insurance Act, approved February 16, 1938, as amended by Public Law No. 691 of the 75th Congress, approved June 22, 1938, the Regulations Relating to Wheat Crop Insurance, as amended,<sup>1</sup> are hereby further amended by the addition of the following parts and sections:

#### "Part 14. Policy Period

"§ 140. Notwithstanding any of the foregoing provisions of these Regulations, the application for wheat crop insurance and the wheat crop insurance policy, insurance under any policy duly countersigned and issued by the Corporation shall attach at 12 o'clock noon on the date of payment of the premium for such policy.

#### "Part 15. Advances for the Payment of Crop Insurance Premiums

"§ 150. *Payment of premiums by means of advances.* Premiums may be paid by means of advances from the Secretary of Agriculture under the provisions of 'An Act to amend Section 12 of the Soil Conservation and Domestic Allotment Act, as amended, by authorizing advances for crop insurance,' approved March 25, 1939. The cash equivalent of such premiums shall be determined in the manner provided for in part 6 of these Regulations and the date for the determination of such cash equivalent shall be the date upon which the request for such advance is made.

"§ 151. *Refund of premiums paid by means of advances.* Refund of any premium or portion thereof which has been paid to the Corporation by means of an advance from the Secretary of Agriculture shall be made to the Secretary of Agriculture for the account of the applicant. The amount of any such refund shall be determined in the manner provided for in part 9 of these Regulations.

"§ 152. *Assignments of policies.* In addition to the provisions relating to assignments of policies under section 106 of these Regulations, assignments of policies to the Secretary of Agriculture may be made to permit the payment to him from any indemnity payable to the insured the amount of advance owing to the Secretary at the time of payment of such indemnity."

Adopted by the Board of Directors on April 28, 1939.

[SEAL] M. L. WILSON,  
Chairman.

Approved May 4, 1939.

H. A. WALLACE,  
Secretary of Agriculture.

[F. R. Doc. 39-1532; Filed, May 5, 1939;  
1:04 p. m.]

## AGRICULTURAL ADJUSTMENT ADMINISTRATION

### AMENDMENTS TO REGULATIONS OF SECRETARY OF AGRICULTURE WITH RESPECT TO RETIREMENT OF COTTON POOL PARTICIPATION TRUST CERTIFICATES, FORM C-5-I

The regulations<sup>1</sup> prescribed by the Secretary of Agriculture with respect to the retirement of Cotton Pool Participation Trust Certificates, Form C-5-I, are hereby amended to conform with the provisions of Public No. 27, 76th Congress, H. R. 3801, a bill to extend the time for retirement of Cotton Pool Participation Trust Certificates, approved April 5, 1939, as follows:

Amend:

Section I by striking out "December 31, 1938," and inserting in lieu thereof, "September 30, 1939".

Section IV by striking out "December 31, 1938," and inserting in lieu thereof, "September 30, 1939".

Section V by striking out "December 31, 1938," and inserting in lieu thereof, "September 30, 1939," wherever "December 31, 1938" appears in Section V.

In witness whereof, I, H. A. Wallace, Secretary of Agriculture, have hereunto set my hand and caused the official seal of the Department of Agriculture to be affixed in the city of Washington, District of Columbia, this 5th day of May 1939.

[SEAL] H. A. WALLACE,  
Secretary of Agriculture.

[F. R. Doc. 39-1543; Filed, May 6, 1939;  
12:15 p. m.]

## TITLE 8—ALIENS AND CITIZENSHIP IMMIGRATION AND NATURALIZATION SERVICE

[5th Sup. to General Order No. C-1<sup>2</sup>]

### DISCONTINUING GATEWAY, MONTANA, AS A PORT OF ENTRY FOR ALIENS

MAY 5, 1939.

Pursuant to the authority contained in Section 23 of the Immigration Act of 1917 (Act of February 5, 1917, 39 Stat. 892; 8 U.S.C. 102), the designation of Gateway, Montana as a port for the entry of aliens into the United States is hereby discontinued.

Sec. 1.31, Title 8, Code of Federal Regulations (Rule 3, Subdivision A, Paragraph 1 of the Immigration Rules and Regulations of January 1, 1930, Edition of December 31, 1936), is amended by eliminating from the list of ports of entry

<sup>1</sup> 3 F.R. 1754 DI.  
<sup>2</sup> 3 F.R. 1657 DI.

in District No. 15, the following: Gateway, Montana.

[SEAL] JAMES L. HOUGHTELING,  
Commissioner of Immigration  
and Naturalization.

Approved:

FRANCES PERKINS,  
Secretary.

[F. R. Doc. 39-1550; Filed, May 8, 1939;  
10:18 a. m.]

## TITLE 16—COMMERCIAL PRACTICES

### FEDERAL TRADE COMMISSION

[Docket No. 3218]

#### IN THE MATTER OF QUALITY BAKERS OF AMERICA ET AL.

**§ 3.45 (e) (1) Discriminating in price—Indirect discrimination—Brokerage payments.** Receiving or accepting, on the part of respondents Quality Bakers of America and Quality Bakers of America, Inc., their officers, etc., and in connection with purchase of commodities in interstate commerce by any [wholesale baker] member of the former or [wholesale baker member] stockholder of the latter, any brokerage fees or commissions or any allowances or discounts in lieu thereof, and granting, paying, transmitting or delivering any such fees, etc., in said connection to such members or stockholders, either directly in the form of money or credits, or indirectly in the form of services, facilities, property or benefits provided or furnished through or by means of expenditure or use of any such brokerage fees, etc., prohibited. (See. 2 (c), 49 Stat. 1527; 15 U.S.C., Sup. IV, sec. 13 (c)) [Cease and desist order, Quality Bakers of America et al., Docket 3218, April 27, 1939]

**§ 3.45 (e) (1) Discriminating in price—Indirect discrimination—Brokerage payments.** Receiving or accepting, on the part of respondent Firch Baking Company, Inc., and five other companies (wholesale baking concerns joined as representative of some sixty-five others in various sections of the United States, and non-competitors), and on the part of the officers, etc., of said respondent companies, and in connection with purchase of commodities by said respondents in interstate commerce, directly or indirectly, from the sellers of such commodities any brokerage fees or commissions or any allowances or discounts in lieu thereof, and receiving or accepting from respondents Quality Bakers of America or Quality Bakers of America, Inc., any brokerage fees, etc., received or accepted by said last-named respondents from such sellers, either in the form of money or credits, or in the form of services, facilities, property or benefits provided or furnished by said last-named respondents, through or by means of the expenditure or use of any such brokerage fees, commissions, allowances or discounts, prohibited. (Sec. 2 (c),

49 Stat. 1527; 15 U.S.C., Supp. IV, sec. 13 (c)) [Cease and desist order, Quality Bakers of America et al., Docket 3218, April 27, 1939]

**§ 3.45 (e) (1) Discriminating in price—Indirect discrimination—Brokerage payments.** Paying or granting, on the part of respondents Pillsbury Flour Mills Company, Consolidated Flour Mills Company and Kansas Milling Company, their officers, etc., and in connection with sales of commodities in interstate commerce to the [wholesale baking] stockholders of respondent Quality Bakers of America, Inc., anything of value to said respondent or to any such stockholder as a commission, brokerage or other compensation, or any allowance or discount in lieu thereof, prohibited. (Sec. 2 (c), 49 Stat. 1527; 15 U.S.C., Supp. IV, sec. 13 (c)) [Cease and desist order, Quality Bakers of America et al., Docket 3218, April 27, 1939]

#### United States of America—Before Federal Trade Commission

At a regular session of the Federal Trade Commission, held at its office in the City of Washington, D. C., on the 27th day of April, A. D. 1939.

Commissioners: Robert E. Freer, Chairman; Garland S. Ferguson, Charles H. March, Ewin L. Davis, William A. Ayres.

IN THE MATTER OF QUALITY BAKERS OF AMERICA, AN UNINCORPORATED ASSOCIATION, AND ITS MEMBERS; FIRCH BAKING CO., INC., DREIKORN BAKERY, INC., THE JACOB LAUB BAKING CO., LIBERTY BAKING CO., STROEHMANN BROTHERS CO., AND VERMONT BAKING CO., INDIVIDUALLY AND AS REPRESENTATIVE MEMBERS OF SAID UNINCORPORATED ASSOCIATION; C. F. STROEHMANN, J. P. DUCHAINE, GROVER C. PATTON AND W. S. ALLISON, AS OFFICERS AND MEMBERS OF THE EXECUTIVE COMMITTEE OF SAID UNINCORPORATED ASSOCIATION, AND E. J. DERST, W. M. CLEMENS, ONIL O. COTE, S. S. WATTERS, HERBERT J. LAUB, JAMES H. SWAN, GEORGE C. WEST, AND JAMES B. DWYER, AS MEMBERS OF SAID EXECUTIVE COMMITTEE, QUALITY BAKERS OF AMERICA, INC., A DELAWARE CORPORATION, WASHBURN CROSBY CO., INC., A CORPORATION, PILLSBURY FLOUR MILLS CO., A CORPORATION, RED STAR MILLING CO., A CORPORATION, CONSOLIDATED FLOUR MILLS CO., A CORPORATION, AND KANSAS MILLING CO., A CORPORATION

#### ORDER TO CEASE AND DESIST

This proceeding having been heard<sup>1</sup> by the Federal Trade Commission upon the complaint of the Commission,<sup>2</sup> the answers of the parties respondent named in the caption hereof, testimony and other evidence, taken before John W. Addison, an Examiner for the Commission theretofore duly designated by it, in support of the allegations of said complaint and in opposition thereto, briefs filed in support of said complaint and in

opposition thereto and the oral arguments of Allen C. Phelps, counsel for the Commission, and Guy C. Heater and Bradshaw Mintener, counsel for certain of the respondents, and the Commission having made its findings as to the facts and its conclusion that the said parties respondent have violated, and are now violating, the provisions of an Act of Congress approved October 15, 1914, entitled "An Act to supplement existing laws against unlawful restraints and monopolies and for other purposes" as amended by an Act of Congress approved June 19, 1936, entitled "An Act to amend Section 2 of the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies and for other purposes' approved October 15, 1914, as amended (U.S.C. Title 15, Sec. 13) and for other purposes":

*It is ordered*, That respondents Quality Bakers of America, an unincorporated association, and Quality Bakers of America, Inc., a corporation, and their respective officers, representatives, agents and employees, in connection with the purchase of commodities in interstate commerce by any member of said Quality Bakers of America or by any stockholder of said Quality Bakers of America, Inc., do forthwith cease and desist from receiving or accepting any brokerage fees or commissions or any allowances or discounts in lieu thereof, and do forthwith cease and desist from granting, paying, transmitting or delivering any such fees, commissions, allowances or discounts to said members or stockholders, either directly in the form of money or credits, or indirectly in the form of services, facilities, property or benefits provided or furnished through or by means of the expenditure or use of any such brokerage fees, commissions, allowances or discounts.

*It is further ordered*, That respondents Firch Baking Company, Inc., Dreikorn Bakery, Inc., The Jacob Laub Baking Company, Liberty Baking Company, Stroehmann Brothers Company and Vermont Baking Company, and their officers, representatives, agents and employees, in connection with the purchase of commodities by said respondents in interstate commerce, do forthwith cease and desist from receiving or accepting from the sellers of such commodities, directly or indirectly, any brokerage fees or commissions or any allowances or discounts in lieu thereof, and from receiving or accepting from respondents Quality Bakers of America or Quality Bakers of America, Inc., any brokerage fees or commissions or any allowances or discounts in lieu thereof, received or accepted by said last-named respondents from such sellers, either in the form of money or credits or in the form of services, facilities, property or benefits provided or furnished by said Quality Bakers of America or Quality Bakers of America, Inc., through or by means of the expenditure or use of any such bro-

<sup>1</sup> 2 F.R. 2237.

<sup>2</sup> 2 F.R. 1829.

kerage fees, commissions, allowances or discounts.

*It is further ordered.* That the complaint herein be, and the same hereby is, dismissed as to the respondents Washburn Crosby Company, Inc. and Red Star Milling Company for the reason that prior to the issuance and service of the complaint herein these respondents were legally dissolved.

*It is further ordered.* That respondents Pillsbury Flour Mills Company, Consolidated Flour Mills Company and Kansas Milling Company and their officers, representatives, agents and employees, in connection with the sales of commodities in interstate commerce to the stockholders of Quality Bakers of America, Inc., do forthwith cease and desist from paying or granting, directly or indirectly, to said Quality Bakers of America, Inc., or to any such stockholder anything of value as a commission, brokerage or other compensation, or any allowance or discount in lieu thereof.

*It is further ordered* That the parties respondent shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with this order.

By the Commission.

[SEAL] OTIS B. JOHNSON,  
Secretary.

[F. R. Doc. 39-1545; Filed, May 6, 1939;  
12:47 p. m.]

*Be it further resolved.* That this amendment is deemed to be of a minor and emergency character within the provisions of subsection (c) of Section 201.2 of the Rules and Regulations for the Federal Savings and Loan System.

Adopted by the Federal Home Loan Bank Board on May 5, 1939.

[SEAL]

R. L. NAGLE,  
Secretary.

[F. R. Doc. 39-1557; Filed, May 8, 1939;  
12:13 p. m.]

#### HOME OWNERS' LOAN CORPORATION

[Administrative Order No. 408]

##### PART 404—APPRaisal LIMITATIONS ON FEES

Amending Part 404 of Title 24 of the Code of Federal Regulations.

Section 404.02-5 is amended to read as follows:

In no one calendar month shall any individual receive fee appraisal assignments the compensation for which exceeds \$400. Expert witness fees and compensation received for other special services in connection with legal proceedings shall be excluded from this limitation. Whenever exceptional circumstances require, for the best interests of the Corporation, the Chief Appraiser may temporarily remove the limitation of \$400, upon the recommendation of the State Manager and State Appraiser, with the concurring approval of the Regional Manager and Regional Appraiser. (Effective April 15, 1939)

Above procedure promulgated by General Manager and General Counsel pursuant to authority vested in them by the Federal Home Loan Bank Board acting pursuant to Home Owners' Loan Act of 1933, 48 Stat. 129, 132, as amended by Section 13 of the Act of April 27, 1934, 48 Stat. 647; 12 U.S.C. 1463 (a), (k).)

Promulgated by the General Manager and General Counsel of Home Owners' Loan Corporation.

[SEAL]

R. L. NAGLE,  
Secretary.

[F. R. Doc. 39-1558; Filed, May 8, 1939;  
12:13 p. m.]

#### TITLE 31—MONEY AND FINANCE: TREASURY

##### PUBLIC DEBT SERVICE

[1939 Department Circular No. 609]

OFFERING OF HOME OWNERS' LOAN CORPORATION  $\frac{3}{8}$  PERCENT BONDS, SERIES K-1940, DUE MAY 15, 1940, AND  $\frac{5}{8}$  PERCENT BONDS, SERIES L-1941, DUE MAY 15, 1941

MAY 8, 1939.

##### I. OFFERING OF BONDS

1. The Secretary of the Treasury, on behalf of the Home Owners' Loan Corpo-

ration, invites subscriptions, at par, from the people of the United States for bonds of the Home Owners' Loan Corporation in two series, designated  $\frac{3}{8}$  percent bonds of Series K-1940 and  $\frac{5}{8}$  percent bonds of Series L-1941 respectively, in payment of which only Home Owners' Loan Corporation  $1\frac{1}{2}$  percent bonds of Series F-1939, maturing June 1, 1939, may be tendered, in multiples of \$100, of which 40 percent will be treated as a subscription for the bonds of Series K-1940 and 60 percent for the bonds of Series L-1941. Where necessary, adjustments will be made to the nearest \$100. The amount of the offering under this circular will be limited to the amount of Home Owners' Loan Corporation bonds of Series F-1939 tendered and accepted. The right is reserved to offer for cash subscription, upon such terms and conditions as may be prescribed by the Home Owners' Loan Corporation with the approval of the Secretary of the Treasury, an additional amount of bonds of either or both issues, approximately equal in the aggregate to the amount of bonds of Series F-1939 not tendered and accepted hereunder.

##### II. DESCRIPTION OF BONDS

1. The bonds of Series K-1940 will be dated May 15, 1939, and will bear interest from that date at the rate of  $\frac{3}{8}$  percent per annum, payable semiannually on November 15, 1939, and May 15, 1940. They will mature May 15, 1940, and will not be subject to call for redemption prior to maturity.

2. The bonds of Series L-1941 will be dated May 15, 1939, and will bear interest from that date at the rate of  $\frac{5}{8}$  percent per annum, payable semiannually on November 15, 1939, and thereafter on May 15 and November 15 in each year until the principal amount becomes payable. They will mature May 15, 1941, and will not be subject to call for redemption prior to maturity.

3. These bonds are issued under the authority of the Home Owners' Loan Act of 1933, as amended, which provides that these bonds shall be exempt, both as to principal and interest, from all taxation (except surtaxes, estate, inheritance, and gift taxes) now or hereafter imposed by the United States or any District, Territory, dependency, or possession thereof, or by any State, county, municipality, or local taxing authority.

4. These bonds are fully and unconditionally guaranteed both as to interest and principal by the United States of America, which guaranty is expressed on the face of each bond.

5. Bearer bonds with interest coupons attached will be issued in denominations of \$100, \$500, \$1,000, \$5,000, \$10,000 and \$100,000. The bonds will not be issued in registered form. Provision will be made for the interchange of bonds of different denominations of the same series, under rules and regulations prescribed by the Corporation.

**TITLE 24—HOUSING CREDIT**  
**FEDERAL HOME LOAN BANK BOARD**  
**AMENDMENT TO RULES AND REGULATIONS  
FOR FEDERAL SAVINGS AND LOAN SYSTEM**  
**PROVIDING THAT ANY FEDERAL ASSOCIATION  
HOLDING, IN ADDITION TO A FIRST MORTGAGE,  
A FURTHER MORTGAGE UPON THE  
SAME REAL ESTATE MAY NOT SELL SUCH  
FIRST MORTGAGE UNLESS IT DISPOSES OF  
ALL MORTGAGES UPON SUCH REAL ESTATE**

*Be it resolved*, That paragraph (d) of Section 203.13 of the Rules and Regulations for the Federal Savings and Loan System is hereby amended, effective May 10, 1939, by adding at the end thereof, the following:

No Federal association which holds a mortgage or other instrument securing a debt which is a first lien upon real estate and which simultaneously holds one or more additional mortgages or other instruments securing a debt and constituting liens inferior to the first lien upon the same real estate, shall sell or otherwise dispose of any such mortgage or other instrument, unless it shall simultaneously sell or otherwise dispose of all mortgages or other instruments constituting inferior liens upon the same real estate. (Sec. 5 (a) of H.O.L.A. of 1933, 48 Stat. 132; 12 U.S.C. 1464 (a).)

## III. SUBSCRIPTION AND ALLOTMENT

1. Subscriptions will be received at the Federal Reserve banks and branches and at the Treasury Department, Washington. Banking institutions generally may submit subscriptions for account of customers, but only the Federal Reserve banks and the Treasury Department are authorized to act as official agencies. The Secretary of the Treasury reserves the right to close the books as to any or all subscriptions or classes of subscriptions at any time without notice.

2. The Secretary of the Treasury reserves the right to reject any subscription, in whole or in part, to allot less than the amount of bonds applied for, to make allotments in full upon applications for smaller amounts and to make reduced allotments upon, or to reject, applications for larger amounts, or to adopt any or all of said methods or such other methods of allotment and classification of allotments as shall be deemed by him to be in the public interest; and his action in any or all of these respects shall be final. Subject to these reservations, all subscriptions will be allotted in full as provided in Section I of this circular. Allotment notices will be sent out promptly upon allotment.

## IV. PAYMENT

1. Payment at par for bonds allotted hereunder must be made or completed on or before May 15, 1939, or on later allotment, and may be made only in Home Owners' Loan Corporation 1½ percent bonds of Series F-1939, which will be accepted at par and should accompany the subscription. Coupons dated June 1, 1939, should be attached to the bonds when surrendered, and accrued interest from December 1, 1938, to May 15, 1939 (\$6.799451 per \$1,000) will be paid following acceptance of the bonds.

## V. GENERAL PROVISIONS

1. As fiscal agents of the United States, Federal Reserve banks are authorized and requested to receive subscriptions, to make allotments on the basis and up to the amounts indicated by the Secretary of the Treasury to the Federal Reserve banks of the respective districts, to issue allotment notices, to receive payment for bonds allotted, to make delivery of bonds on full-paid subscriptions allotted, and they may issue interim receipts pending delivery of the definitive bonds.

2. The Secretary of the Treasury may at any time, or from time to time, prescribe supplemental or amendatory rules and regulations governing the offering, which will be communicated promptly to the Federal Reserve banks.

[SEAL] HENRY MORGENTHAU, Jr.,  
Secretary of the Treasury.

[F. R. Doc. 39-1556; Filed, May 8, 1939;  
12:01 p. m.]

## Notices

## TREASURY DEPARTMENT.

## Bureau of Customs.

[T. D. 49855]

WELLESLEY FARMS AIRPORT AND WELLESLEY ISLAND SEAPLANE BASE, WELLESLEY ISLAND, NEW YORK, REDESIGNATED AS AIRPORTS OF ENTRY FOR A PERIOD OF ONE YEAR

MAY 1, 1939.

To Collectors of Customs and Others Concerned:

Under the authority of section 7 (b) of the Air Commerce Act of 1926 (U.S.C., title 49, sec. 177 (b)), the Wellesley Farms Airport and the Wellesley Island Seaplane Base, Wellesley Island, New York, are hereby redesignated as airports of entry for civil aircraft and merchandise carried thereon arriving from places outside the United States, as defined in section 9 (b) of the said act (U.S.C., title 49, sec. 179 (b)), for a period of one year from May 1, 1939.

[SEAL] STEPHEN B. GIBBONS,  
Acting Secretary of the Treasury.

[F. R. Doc. 39-1542; Filed, May 6, 1939;  
11:07 a. m.]

## Federal Alcohol Administration Division.

DIGEST OF INTERPRETATIONS OF REGULATIONS NO. 8, PRESCRIBING CREDIT PERIOD TO BE EXTENDED TO RETAILERS OF ALCOHOLIC BEVERAGES, AS OF APRIL 1, 1939

MAY 5, 1939.

To All Industry Members:

There is enclosed herewith for the information and guidance of all concerned, a digest of interpretations of Regulations No. 8,<sup>1</sup> prescribing the credit period to be extended to retailers of alcoholic beverages.

This digest is issued in view of the fact that the Administration has received numerous inquiries from producers, wholesalers, and others, many of which contain the same questions and indicate that there may be some confusion as to the purposes and effect of these regulations.

The rulings contained in this digest are summarized from letters addressed by the Administration in response to inquiries which it has received. The opinions expressed in this digest are, of course, subject to revision or modification by the Administration at any time. The digest is issued to aid the industry in a more complete understanding of the regulations and to obviate the necessity

of addressing specific inquiries in connection with the subjects covered.

[SEAL] W. S. ALEXANDER,  
Administrator.

## HISTORY OF REGULATIONS

These regulations are issued pursuant to the provisions of section 5 (b) (6) of the Federal Alcohol Administration Act, which provides in part that it is unlawful for any producer, importer, or wholesaler of distilled spirits, wine, or malt beverages to induce any retailer engaged in the sale of such beverages to purchase any such products from such person to the exclusion, in whole or in part, of such products sold or offered for sale by other persons in interstate or foreign commerce "by extending to the retailer credit for a period in excess of the credit period usual and customary to the industry for the particular class of transaction, as ascertained by the Administrator and prescribed by regulations by him." These regulations were issued on the basis of evidence adduced at a public hearing held, pursuant to due notice to all concerned, in Washington, D. C., on April 26, 1938, and prescribed as the credit period usual and customary to the industry a period of thirty days from date of delivery.

## PURPOSE OF THE REGULATIONS

The object of the statute and regulations is to prevent the establishment of "tied-house" relationships between the vendor and retailer through the extension of credit to the retailer beyond the period found to be usual and customary to the trade. It is not the purpose of the regulations to preclude credit as such in its normal commercial and necessary use.

Of course, an extension of credit beyond that found usual and customary which tends to make a retailer prefer to deal with a particular firm that offers a credit concession rather than with other concerns would therefore have the effect of encouraging the "tied-house" relationships between producers, importers, or wholesalers and retailers distributing their products, which it is the purpose of the statute to prevent.

## EFFECTIVE DATE

The regulations became effective, with respect to future transactions, on March 1, 1939. Therefore, transactions consummated on or after March 1, 1939, are subject to the regulations.

The regulations provide that with respect to deliveries heretofore consummated that they shall take effect twelve months after the date of filing with the Division of the Federal Register. Thus, the regulations have the same effective date with respect to deliveries of alcoholic beverages consummated prior to March 1, 1939, as to deliveries consummated before November 30, 1938. There-

fore, with respect to transactions consummated prior to March 1, 1939, the regulations become effective on November 30, 1939.

#### APPLICATION OF REGULATIONS TO DELIVERIES OF MALT BEVERAGES

In the case of malt beverages, the provisions of subsection (b) of section 5 of the Act apply to transactions between a retailer in any State and a brewer, importer, or wholesaler of malt beverages outside such State only to the extent that the law of such State imposes similar requirements with respect to similar transactions between a retailer in such State and a brewer, importer, or wholesaler in such State, as the case may be. Therefore, the regulations apply only to shipments of malt beverages into a State which has adopted requirements similar to those contained in Regulations No. 8, and do not apply to transactions involving malt beverages which are limited to the boundaries of a single State.

With respect to shipments of malt beverages into a State which has adopted credit regulations, Regulations No. 8 would apply in situations involving the extension of a period of credit which violates both the Federal and State regulations.

#### MEASUREMENT OF PERIOD

The period of credit is measured by the time elapsing between the date on which the alcoholic beverages were delivered to the retailer and the date when the retailer completely discharges his indebtedness by payment in cash or its equivalent.

#### SUMMARY OF RULINGS ON APPLICATION OF REGULATIONS

[Condensed into question and answer form]

1. Do the regulations prohibit in all instances the extension of credit for a greater period than 30 days?

No. The regulations do not establish a fixed period of credit. They ascertain, under the statute, the period of credit usual and customary to the industry as being 30 days from date of delivery, and prohibit producers, importers, and wholesalers of alcoholic beverages from extending a greater period of credit only when such extension results in inducing a retailer to purchase the products of a particular vendor to the exclusion of the products of others sold in interstate or foreign commerce.

2. Do the regulations prohibit a wholesaler from continuing to sell alcoholic beverages to a retailer who has not paid his bills within 30 days, or to deal with such retailer upon a cash or c. o. d. basis?

No. They do not prohibit any wholesaler from shipping to a retailer who is in arrears, provided, of course, that the wholesaler does not induce the retailer to deal with him by offering him credit for more than 30 days. Similarly, they do not prevent other wholesalers from

selling merchandise to a retailer who is in arrears.

3. Do the regulations require members of the industry to furnish the Administration with a list of retailers who have not paid their bills within 30 days?

No. The regulations at present do not require that any reports be furnished to the Administration.

4. Do the regulations apply to sales to retailers in the same State in which the wholesaler is located?

The regulations apply primarily to all persons who hold permits issued by this Administration. Therefore, their application does not necessarily depend upon interstate shipments.

With respect to intrastate sales of malt beverages, see the paragraph on malt beverages in the introduction.

5. Do the regulations apply to wholesalers who conduct a purely intrastate business?

See reply to preceding question.

6. Do the regulations conflict with State regulations limiting the period of credit which may be offered to retailers?

No. It is not within the Administration's province to interpret or construe State regulations as have come to the attention of the Administration appear, from a factual and practical standpoint, to place a definite limit upon the period of credit which may be offered to, or received by, retailers. The Federal regulations, however, do not constitute a specific limitation on the period of credit, but are in the nature of a contingent limitation, depending in their application upon the results flowing from such extension of credit. Under this Administration's regulations credit may be extended beyond the period found usual and customary to the industry, provided that such extension does not tend to result in the conditions prescribed by the statute. The State regulations fix a maximum credit period, whereas this Administration's regulations do not fix a maximum credit term, nor is it the intent of the statute that they should do so.

In ordinary circumstances involving the extension of credit for customary and legitimate purposes, the granting of credit for the full period allowed by a State regulation would appear to involve no violation of this Administration's regulations, even though the State regulations established a credit period which was greater than 30 days. However, should such an extension of credit result in inducing a retailer to purchase a particular vendor's products to the exclusion of the products of others, *an extension of credit for a period of time in excess of 30 days from date of delivery might be unlawful.*

It should also be noted that neither the Federal nor State regulations affirmatively require members of the industry to offer the full period of credit

specified therein. Thus, a shorter period of credit could, under State regulations, be offered a retailer in cases where the extension of a longer period would violate the Federal regulations.

7. Do the regulations require producers, importers, or wholesalers to extend the full period of credit?

No. The regulations should not be construed as affecting the right of individual industry members to grant or establish credit periods of less than 30 days, since it is not the purpose of the statute to fix a credit term.

8. Do the regulations authorize retailers to demand 30 days' credit?

No. The regulations impose no duties upon, and grant no privileges to, retailers. (See answer to above question.)

9. Do the regulations apply to retailers?

The regulations apply to transactions between producers, importers, or wholesalers of alcoholic beverages and retailers, whether such persons are parties to the transaction directly or indirectly through an affiliate. Retailers are not required to obtain permits from the Federal Alcohol Administration and these regulations are not imposed upon them.

10. Do the regulations require retailers to pay bills within 30 days?

The regulations contain no provisions which will require retailers to pay their accounts within the 30-day period found usual and customary to the industry.

11. Will the Administration enforce agreements on the part of associations or other groups in the industry to offer no greater period of credit to retailers than 30 days, and to discontinue dealing with any retailer who does not pay within 30 days?

No. The Administration has no power to regulate the rules and regulations adopted by associations composed of producers, importers, or wholesalers of alcoholic beverages, nor has it the power to enforce such rules. If a violation of the rules in question also involves a violation of the Federal statute or regulations, the Administration would then take action with respect to the latter aspect of the situation.

12. Would the Administration approve of the use upon invoices of a statement similar to the following: "Federal regulations require payment within 30 days"?

You will note that the regulations contain no provisions which will require retailers to pay their accounts within the period found usual and customary. In view of the fact that the regulations are not imposed upon retailers, the Administration cannot give its approval to the use of such a statement.

13. Do the regulations authorize retailers to postpone until November 30, 1939, payment for deliveries of alcoholic beverages made prior to March 1, 1939?

This interpretation of the regulations is contrary to their spirit and letter. Indeed, Section 5 (b) (6) of the statute, and Regulations No. 8, which were promulgated thereunder, do not convey any rights or privileges to retailers as such to demand credit or the extension thereof.

14. Do the regulations apply to an extension of credit by retailers to consumers?

No. They apply only to transactions involving purchases by retailers.

15. Do the regulations apply to extensions of credit by all holders of wholesale liquor dealer's tax stamps?

In so far as wholesalers of alcoholic beverages are concerned, these regulations apply to all persons holding permits from this Administration. Under the Federal Alcohol Administration Act permits must be obtained by everyone who is engaged in the business of purchasing alcoholic beverages for resale at wholesale. Thus, the regulations apply to wholesalers regardless of whether or not they have paid for a wholesaler or retail liquor dealer's tax stamp. Similarly, regardless of tax stamps, the regulations affect transactions with retailers, i. e., persons who sell alcoholic beverages to the consuming public and not for resale.

16. Do the regulations apply to transactions with State liquor monopolies?

If the extension of credit for a period of greater than 30 days to a particular State liquor monopoly results in inducing the monopoly to purchase the products of a particular vendor to the exclusion of alcoholic beverages sold by others in interstate or foreign commerce, under the conditions prescribed by the statute, a violation of the regulations would result.

17. Do the regulations apply to sales of wine to members of the clergy for sacramental use?

With respect to such sales, a company cannot be considered as extending credit to a retailer, assuming, of course, that the purchaser of the wine will not resell it.

18. Do Regulations No. 8 apply to commodities other than alcoholic beverages as defined by the Federal Alcohol Administration Act?

No. This provision in the Act does not apply to the sale of any products other than distilled spirits, wine, or malt beverages.

19. Do the regulations prevent the customary extension of more than 30 days credit upon shipments of alcoholic beverages to Alaska or to other regions relatively isolated, due to their geographical location or climatic conditions?

If in fact the extension of a period of credit greater than 30 days is usual and customary in Alaska and does not have

the results prohibited by the statute, the granting thereof would not violate these regulations.

From the above, it is apparent that it is not necessary to specifically exempt from the regulations wholesalers who ship alcoholic beverages to Alaska.

20. Do the regulations apply to wholesalers and other members of the industry who sell to retailers in Hawaii, Alaska, and Puerto Rico?

In this connection you are advised that the regulations in question are applicable to all persons holding permits issued by the Administration. In view of the fact that the Federal Alcohol Administration Act applies to Hawaii, Alaska, and Puerto Rico, the regulations would also apply to wholesalers doing business therein.

21. Have retailers been notified by the Administration of the issuance of Regulations No. 8?

Inasmuch as the regulations do not attempt to fix a reasonable term of credit nor are they intended to assist wholesalers in the collection of accounts, the Administration would not be justified in specifically notifying retailers of their issuance.

22. Would acceptance of the retailer's note for the amount of his indebtedness constitute full legal discharge under Regulations No. 8?

No. Such notes are not the equivalent of cash.

23. Is the intent of the seller the primary consideration in determining whether or not an extension of credit results in inducing purchases by retailers?

In attempting to ascertain whether or not the regulations and statute have been violated, the Administration will consider all factors which are reasonable and which have received the approval of the courts in the determination of such matters by administrative agencies.

24. What extension of credit will result in inducing purchases by a retailer?

Whether or not a particular extension of credit results in the inducement prescribed by the statute cannot be decided by the Administration in advance.

25. What period is provided for the liquidation of indebtedness resulting from deliveries of alcoholic beverages prior to March 1, 1939?

Section 4 of the regulations provides that such transactions may be liquidated within one year after the date of filing with the Division of the Federal Register (November 30, 1938), and also provides that after such period they may be further liquidated under such terms as in the opinion of the Administrator would not conflict with the requirements of the statute.

26. How does the Administration intend to enforce the 30-day period?

The Administration expects to enforce Regulations No. 8 in the same manner as it enforces all other regulations, by the means provided in the statute.

27. What penalties might be incurred as a result of a violation of the regulations?

All importers, distillers, rectifiers, wine producers, and wholesalers are required, under the statute, to secure basic permits from this Administration, authorizing their operations. One of the conditions in such basic permit is compliance with the credit provision of the statute, and the basic permit may be suspended by the Administrator for a violation of this condition or revoked for repeated violations. Moreover, the statute provides that any person violating this provision shall be guilty of a misdemeanor and, upon conviction thereof, shall be fined not more than \$1,000. The Administrator, with the approval of the Attorney General, is authorized to compromise the liability arising with respect to violations of this provision.

[F. R. Doc. 39-1540; Filed, May 5, 1939; 4:10 p. m.]

## DEPARTMENT OF LABOR.

### Division of Public Contracts.

#### IN THE MATTER OF THE DETERMINATION OF THE PREVAILING MINIMUM WAGES IN THE CEREAL-PREPARED INDUSTRY

##### NOTICE OF HEARING

The Public Contracts Board will hold a hearing in Room 3135, Department of Labor Building, Washington, D. C., at 10:00 a. m., Tuesday, May 23, 1939, to take testimony upon which findings of fact will be made to assist the Secretary of Labor in determining, pursuant to Section 1 (b) of the Public Contracts Act,<sup>1</sup> the prevailing minimum wages in the Cereal - Preparations Industry. The Cereal-Preparations Industry shall be understood to be that industry which manufacturers from wheat, oats, corn, and other grains, "breakfast foods," coffee substitutes, flakes and grits for brewers' use, and similar preparations.

A copy of the report of the Women's Bureau on the Wages and Hours in the Cereal-Preparations Industry, 1938, will be introduced in evidence at the hearing in this matter.<sup>2</sup>

At the hearing an opportunity to be heard, either in person or by duly appointed representatives, will be given to persons engaged in the above-named industry, either as employers or as employees, to groups of such persons, and to others within the discretion of the

<sup>1</sup> 49 Stat. 2036; 41 U.S.C. Sup. III 35.

<sup>2</sup> Copies of this report will be supplied upon request addressed to the Administrator, Division of Public Contracts.

Board. Briefs or telegraphic communications may be filed, but they should be received by the Administrator, Division of Public Contracts, on or before the hearing date. Five copies of all briefs must be submitted. Employers appearing in person, or by representatives, or presenting briefs, should furnish the Board with the following essential data:

- (1) Name of firm.
- (2) Plant address.
- (3) Total number of employees in plant.
- (4) Number of male employees.
- (5) Number of female employees.
- (6) Classification of employees by occupations, including number engaged in such operation.
- (7) Hourly wages in each operation with designation of applicable time period.
- (8) If paid on piece work basis, weekly earnings in each class of employees.
- (9) Hours worked per week.

This outline of suggested data is not meant to exclude the submission of any other pertinent information which an employer may desire to submit.

Employees appearing at the hearing, either in person or by their representatives, or submitting briefs, should acquaint the Board with facts as to the wages now being paid in the industry.

[SEAL] WM. R. McCOMB,  
Acting Administrator.

Dated: May 6, 1939.

[F. R. Doc. 39-1551; Filed, May 8, 1939;  
10:18 a. m.]

#### Wage and Hour Division.

[Administrative Order No. 22]

#### AMENDING DEFINITION OF "HAT INDUSTRY" AS CONTAINED IN ADMINISTRATIVE ORDER NO. 16 APPOINTING INDUSTRY COMMITTEE NO. 4

By virtue of and pursuant to the authority vested in me by the "Fair Labor Standards Act of 1938," I, Elmer F. Andrews, Administrator of the Wage and Hour Division, Department of Labor, do hereby amend the definition of the term "hat industry" as contained in paragraph 2 of Administrative Order No. 16, dated March 7, 1939,<sup>1</sup> to read as follows:

As used in this order, the term "hat industry" means

- (a) The manufacture from any material of headwear for men or boys, except caps and cloth hats.
- (b) The manufacture of felt hat bodies from fur or wool for men's, boys', women's or children's hats.
- (c) The manufacture or processing of hatters' furs.

<sup>1</sup> 4 F.R. 1186 D.L.

No. 89—5

Signed at Washington, D. C., this 6th day of May 1939.

ELMER F. ANDREWS,  
Administrator.

[F. R. Doc. 39-1554; Filed, May 8, 1939;  
11:01 a. m.]

[Administrative Order No. 23]

#### AMENDING DEFINITION OF "MILLINERY INDUSTRY" AS CONTAINED IN ADMINISTRATIVE ORDER NO. 17 APPOINTING INDUSTRY COMMITTEE NO. 5

By virtue of and pursuant to the authority vested in me by the "Fair Labor Standards Act of 1938," I, Elmer F. Andrews, Administrator of the Wage and Hour Division, Department of Labor, do hereby amend the definition of the term "millinery industry" as contained in paragraph 2 of Administrative Order No. 17, dated March 7, 1939,<sup>1</sup> to read as follows:

As used in this order, the term "millinery industry" means

The manufacture of all headwear, except knitted headwear, for ladies, misses, girls and infants, from any material, but not including the manufacture of felt hat bodies of fur or wool.

Signed at Washington, D. C., this 6th day of May, 1939.

ELMER F. ANDREWS,  
Administrator.

[F. R. Doc. 39-1555; Filed, May 8, 1939;  
11:01 a. m.]

#### RENOTICE OF PUBLIC HEARING BEFORE INDUSTRY COMMITTEE NO. 4 FOR PURPOSE OF RECEIVING EVIDENCE TO BE CONSIDERED IN RECOMMENDING MINIMUM WAGE RATES FOR THE HAT INDUSTRY

In conformity with the Fair Labor Standards Act of 1938, 52 Stat. 1060, and Section 511.11 of Part 511 of the Rules and Regulations issued pursuant thereto,<sup>2</sup> notice is hereby given to all interested persons that a public hearing will be held beginning at 11 A. M., May 15, 1939, in the Hotel Washington, 15th Street and Pennsylvania Avenue NW., Washington, D. C., for the purpose of receiving evidence to be considered by Industry Committee No. 4 in determining the highest minimum wage rates for the hat industry which, with due regard to economic and competitive conditions, will not substantially curtail employment.

The term "hat industry" originally defined in Administrative Order No. 16, issued March 7, 1939, has been redefined in Administrative Order No. 22, issued May 6, 1939, as follows:

- (a) The manufacture from any material of headwear for men or boys, except caps and cloth hats.

(b) The manufacture of felt hat bodies from fur or wool for men's, boys', women's or children's hats.

(c) The manufacture or processing of hatters' furs.

Industry Committee No. 4 was created by Administrative Order No. 16, referred to above. It is charged, in accordance with the provisions of the Fair Labor Standards Act of 1938 and rules and regulations promulgated thereunder, with the duty of investigating conditions in the hat industry and recommending to the Administrator minimum wage rates for all employees thereof who within the meaning of said Act are "engaged in commerce or in the production of goods for commerce," excepting employees exempted by the provisions of Section 13 (a) and employees coming under the provisions of Section 14.

Any interested person may appear on his own behalf or on behalf of any other person. Persons desiring to appear are requested to file with Burton E. Oppenheim, Chief of the Industry Committee Section, Wage and Hour Division, U. S. Department of Labor, Washington, D. C., prior to May 12, 1939, a Notice of Intention to Appear containing the following information:

- (1) The name and address of the person appearing.
- (2) If he is appearing in a representative capacity, the name and address of the person or persons whom he is representing.
- (3) The approximate length of time which his presentation will consume.

Signed at Middletown, Connecticut, this 8th day of May 1939.

C. O. FISHER,  
Chairman, Industry Committee  
No. 4 for the Hat Industry.

[F. R. Doc. 39-1553; Filed, May 8, 1939;  
11:01 a. m.]

#### CIVIL AERONAUTICS AUTHORITY.

#### AMENDMENT NO. 1 OF SPECIAL TRAFFIC RULE CAA NO. 4 UNDER SECTION 601 (A) (7)<sup>1</sup>

##### NEW YORK WORLD'S FAIR OF 1939

At a session of the Civil Aeronautics Authority held at its office in Washington, D. C., on the 5th day of May 1939.

It appearing that: The boundaries designating the limits of the area surrounding the fair grounds of the New York World's Fair of 1939, Inc., within which flight of aircraft is restricted by Special Traffic Rule CAA No. 4, are not sufficiently definite, and it is necessary for the Authority to more specifically designate such boundaries.

The Authority finds that: To promote safety of flight in air commerce it is necessary to further define the boundaries surrounding the fair grounds of the New York World's Fair of 1939, Inc.

<sup>1</sup> 4 FR. 165 D.L.

<sup>2</sup> 4 F.R. 1187 D.L.

within which flight of aircraft is restricted.

Now, therefore, the Civil Aeronautics Authority, acting pursuant to the authority vested in it by the Civil Aeronautics Act of 1938, particularly section 205 (a) and section 601 (a) (7) of said Act hereby amends Special Traffic Rule CAA No. 4 so that the boundaries designated therein will be as follows:

*Boundaries*

*North*.—Imaginary line from the Flushing illuminating gas tank, which tank is marked on the top thereof with the word "Flushing," west to intersection of Astoria Boulevard and 31st Avenue.

*West*.—Imaginary line from intersection of Astoria Boulevard and 31st Avenue, south to Forest Hills Tennis Stadium.

*South*.—Long Island Railroad tracks from Forest Hills Tennis Stadium, southeast to Kew Gardens Railroad Station, Kew Gardens Railroad Station east to intersection of Grand Central Parkway and Main Street.

*East*.—Main Street from Grand Central Parkway intersection, north to said Flushing illuminating gas tank.

Dated at Washington, D. C., this 5th day of May 1939.

By the Authority.

[SEAL] PAUL J. FRIZZELL,  
Secretary.

[F. R. Doc. 39-1548; Filed, May 6, 1939;  
12:56 p. m.]

[Docket No. 231]

IN THE MATTER OF THE PETITION OF CONTINENTAL AIR LINES, INC., FOR AN ORDER FIXING AND DETERMINING THE FAIR AND REASONABLE RATES OF COMPENSATION FOR THE TRANSPORTATION OF MAIL OVER ROUTE NO. 43

*NOTICE OF HEARING*

The above-entitled proceeding is assigned for public hearing on May 15, 1939, 10 o'clock a. m. (Eastern Standard Time) at the Carlton Hotel, 923 16th Street NW, Washington, D. C., before C. Edward Leasure, Examiner.

Dated Washington, D. C., May 6, 1939.  
By the Authority.

[SEAL] PAUL J. FRIZZELL,  
Secretary.

[F. R. Doc. 39-1547; Filed, May 6, 1939;  
12:56 p. m.]

[Docket No. 233]

IN THE MATTER OF THE AIR TRAVEL CARD PLAN OF CERTAIN AIR CARRIERS  
ORDER FOR GENERAL INVESTIGATION AND  
HEARING

At a session of the Civil Aeronautics Authority held in the City of Washington, D. C., on the 6th day of May 1939.

Acting upon its own initiative and pursuant to the powers and duties vested in it under Titles IV and X of the Civil Aeronautics Act of 1938;

And it appearing to the Authority that:

(1) On October 1, 1938 a certain agreement between American Airlines, Inc., Boston-Maine Airways, Inc., including Central Vermont Airways division (formerly National Airways, Inc.), Braniff Airways, Inc., Canadian-Colonial Airways, Inc., Canadian-Colonial Airways, Ltd., Chicago and Southern Air Lines, Inc., Continental Air Lines, Inc., Delta Air Corporation (operator of Delta Air Lines), Eastern Air Lines, Inc. (formerly Eastern Air Lines Division of North American Aviation, Inc.), Inland Air Lines, Inc. (formerly Wyoming Air Service, Inc.), Mid-Continent Airlines, Inc. (formerly Hanford Airlines, Inc.), Northwest Airlines, Inc., Pennsylvania-Central Airlines Corp., Trans-Canada Air Lines, Transcontinental and Western Air, Inc., United Air Lines Transport Corp., and Western Air Express Corporation has been filed with the Authority pursuant to section 412 (a) of the Civil Aeronautics Act of 1938 and that said agreement provides, among other things, for an Air Travel Card Plan under which Air Travel Contracts are issued by certain of the above-named air carriers and honored by both said issuing carriers and by certain others of the above-named carriers who are participating parties to the agreement and whereby passengers obtain certain discounts from the fares otherwise provided in the said carriers' tariffs in consideration of the deposit in advance of certain sums of money by the passengers, and

(2) Said agreement as originally filed was amended on December 22, 1938 to include as a party thereto National Airlines, Inc., and that on February 13, 1939, a second amendment was filed eliminating certain provisions of the original agreement as to the use of script, and

(3) In addition to said agreement and in accordance with the terms thereof there are tariffs presently filed by all of the aforesaid carriers and also by Airline Feeder System, Inc., providing for a 15% discount to passengers holding Air Travel Contracts with carriers on the one way fares of said passengers and also providing for other discounts to said passengers, and

(4) A form of said Air Travel Contract, as referred to in said tariffs, is on file with the Authority;

The Authority finds it desirable in the public interest and in order to carry out the provisions of, and to exercise and perform its powers and duties under, said Act to investigate the aforesaid matters;

Now, therefore, it is ordered. That an immediate general investigation be in-

stituted as to said agreement, Air Travel Card Plan, Air Travel Contracts, tariffs, and all amendments and supplements thereto, and all practices in connection therewith; and that the aforesaid matters be set for hearing at such time and place as shall hereafter be fixed;

And it is further ordered. That all of the above-named air carriers are made respondents.

By the Authority.

[SEAL]

PAUL J. FRIZZELL,  
Secretary.

[F. R. Doc. 39-1559; Filed, May 8, 1939;  
12:18 p. m.]

FEDERAL POWER COMMISSION.

[Docket No. ID-520]

IN THE MATTER OF HORACE P. LIVERSIDGE  
ORDER FIXING DATE OF HEARING

MAY 5, 1939.

Commissioners: Clyde L. Seavey, Acting Chairman; Claude L. Draper, John W. Scott. Basil Manly, not participating.

It appearing to the Commission that:

(a) Upon supplemental application of Horace P. Liversidge, 1000 Chestnut Street, Philadelphia, Pennsylvania, filed October 26, 1938, and amendment thereto filed January 25, 1939, pursuant to Section 305 (b) of the Federal Power Act, for authorization to hold the following positions:

President, Philadelphia Electric Company.

President, Philadelphia Electric Power Company.

President, The Susquehanna Power Company.

President, The Susquehanna Electric Company.

President, Deep Water Light & Power Company.

which application supplements applications heretofore filed on October 25, 1935, December 16, 1935, and March 9, 1936, for authorization to hold the following positions:

Vice-President-Director, Philadelphia Electric Company.

Vice-President-Director, Philadelphia Electric Power Company.

Vice-President-Director, The Susquehanna Power Company.

Vice-President-Director, The Susquehanna Electric Company.

Vice-President-Director, Deep Water Light & Power Company.

and upon which applications filed October 25, 1935, December 16, 1935, and March 9, 1936, authorization was granted by the Commission's orders dated February 18, 1936, and March 24, 1936, which orders of authorization reserve to the Commission the right to require the applicant to make further showing that

neither public nor private interest will be adversely affected by reason of the applicant's holding said positions;

(b) It is in the public interest that the above-named applicant make further showing at this time that neither public nor private interest will be adversely affected by reason of his holding said positions for which authorization has heretofore been granted or those for which authorization is sought by the application filed October 26, 1938, and amendment thereto filed January 25, 1939;

(c) Such further showing can best be made in the form and manner of a public hearing for that purpose.

And the Commission orders that:

A public hearing on said application be held beginning on the 5th day of June 1939, at 10:00 a. m., in the hearing room of the Commission, 1757 K Street NW, Washington, D. C., and that at said hearing the above-named applicant make further showing that neither public nor private interest will be adversely affected by reason of his holding positions within the purview of Section 305 (b) of the Federal Power Act.

By the Commission.

[SEAL]

LEON M. FUQUAY,  
Secretary.

[F. R. Doc. 39-1541; Filed, May 6, 1939;  
10:29 a. m.]

#### SECURITIES AND EXCHANGE COMMISSION.

*United States of America—Before the Securities and Exchange Commission*

At a regular session of the Securities and Exchange Commission held at its office in the City of Washington, D. C., on the 6th day of May, A. D. 1939.

[File No. 46-138]

#### IN THE MATTER OF INTERNATIONAL UTILITIES CORPORATION

##### NOTICE OF AND ORDER FOR HEARING

An application pursuant to section 10 (a) (1) of the Public Utility Holding Company Act of 1935, having been duly filed with this Commission by the above-named party:

*It is ordered*, That a hearing on such matter be held on May 15, 1939, at 10:00 o'clock in the forenoon of that day, at the Securities and Exchange Building, 1778 Pennsylvania Avenue, NW, Washington, D. C. On such day the hearing-room clerk in room 1102 will advise as to the room where such hearing will be held. At such hearing, if in respect of any declaration, cause shall be shown why such declaration shall become effective.

*It is further ordered*, That Robert P. Reeder or any other officer or officers of the Commission designated by it for that purpose shall preside at the hearings in such matter. The officer so designated

to preside at any such hearing is hereby authorized to exercise all powers granted to the Commission under section 18 (c) of said Act and to a trial examiner under the Commission's Rules of Practice to continue or postpone said hearing from time to time.

Notice of such hearing is hereby given to such declarant or applicant and to any other person whose participation in such proceeding may be in the public interest or for the protection of investors or consumers. It is requested that any person desiring to be heard or to be admitted as a party to such proceeding shall file a notice to that effect with the Commission on or before May 13, 1939.

The matter concerned herewith is in regard to an application by International Utilities Corporation pursuant to Section 10 (a) (1) of the Public Utility Holding Company Act of 1935 for the approval of the acquisition by it of \$173,000 First Mortgage 4½% Sinking Fund Bonds, Series A, due June 1, 1939, of Northwestern Utilities Limited, Edmonton, Alberta, Canada, which are to be acquired in exchange for \$173,000 First Mortgage 5½% Sinking Fund Bonds, Series B, due June 1, 1949, also issued by Northwestern Utilities Limited.

By the Commission.

[SEAL]

FRANCIS P. BRASSOR,  
Secretary.

[F. R. Doc. 39-1552; Filed, May 8, 1939;  
10:49 a. m.]

